


Medicare Participating Heart Bypass Center Demonstration:

Appropriateness Study - Review of Literature For Efficacy and Risks of PTCA

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Chapter 1

INTRODUCTION AND METHODS

The purpose of this review is to summarize, for a panel of experts, what research published from 1982 to October, 1990 has to say about PTCA with respect to its efficacy, complications, costs, utilization, and indications. Therefore, only articles with information on these topics are included. The panelists will use the information contained in this review, together with their expert opinion to rate indications for the use of angioplasty according to how appropriate they are in 1990.

We began this review with a search of the MEDLINE, a computerized, bibliographic database of the National Library of Medicine. Next, the references in the articles identified by the MEDLINE search were examined. Finally, members of the New York Cardiac Advisory Committee, the Academic Medical Center Consortium and relevant medical specialty societies have been asked to evaluate both the bibliography for accuracy and completeness and the literature review for accuracy.

This review includes 331 papers. The distribution by year of publication and study type is shown in table 1.1

The publications were classified into original research studies, editorials, and reviews. Original research studies that contained primary data were further subclassified as randomized, controlled trials (RCT), prospective, non-RCT studies (excluding registries), prospective, non-RCT registry studies, case-control/retrospective adjusted cohort studies, and observational/unadjusted retrospective studies. Papers which did not explicitly identify that data was prospectively collected were classified as retrospective. Additional categories included cross-sectional studies and surveys. Defining characteristics for assigning references according to this classification system were:

- o *Randomized controlled trials.* Subjects are randomly assigned to one or more experimental and control groups and all data are collected prospectively.
- o *Prospective non-RCT cohort studies.* The research is organized at a certain point in time, all data are collected thereafter. Subjects are not randomly assigned to study groups.
- o *Prospective non-RCT registry studies.* These are also prospective historical or adjusted cohort studies, but the data are collected at multiple centers and tabulated at a central registry location. Subjects are not randomly assigned.
- o *Retrospective adjusted cohort and case control studies.* These are research studies in which the data are collected after the events being studied have taken place. Patients are identified according to presentation or treatment and then a control group of patients without CABG are selected with similar characteristics.
- o *Observational and unadjusted retrospective cohort studies.* These are uncontrolled reports of outcomes of a series of patients with the treatment of interest. Patients are usually selected consecutively, with data gathered prospectively or retrospectively. Included in this group are studies where patients are identified retrospectively and outcomes in "experimental" patients are compared to contemporaneous patients who do not receive the treatment.
- o *Survey.* In the context of this review, a survey study is the results of a questionnaire sent to practicing physicians regarding the treatment of cardiovascular disease.
- o *Editorials.* Essays describing personal viewpoints concerning CABG.
- o *Reviews.* Compendia of research about CABG.

TABLE 1.1
DISTRIBUTION OF RESEARCH ARTICLES
ON PERCUTANEOUS TRANSLUMINAL CORONARY
ANGIOPLASTY BY YEAR OF PUBLICATION AND
METHOD USED TO COLLECT OR REVIEW DATA

Paper Class	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	Total
Review	0	0	0	2	3	4	4	5	16	14	11	59
Editorial	0	0	0	1	2	3	1	4	2	4	5	22
Prospective RCT	0	0	0	0	1	1	2	4	2	1	2	13
Prospective, Non-RCT	0	0	1	3	4	5	5	6	11	8	3	46
Prospective, Registry	0	0	2	4	13	2	1	1	3	4	7	37
Case Control & Adjusted cohort	0	0	1	2	0	0	2	2	4	5	2	18
Observational	1	1	1	3	12	12	12	27	25	29	8	131
Cross Sectional	0	0	0	0	0	0	0	2	1	0	0	3
Survey	0	0	0	0	0	0	0	0	1	0	1	2
Year Totals	1	1	5	15	35	27	27	51	65	65	39	331

Because angioplasty is a relatively new technique compared to coronary artery bypass surgery, definitive, randomized controlled long-range studies to determine PTCA efficacy are still underway. [17] The majority of the data in this review, therefore, is drawn from uncontrolled studies. We have elected to be less selective in our selection of publications included in this review compared to the companion work on coronary artery bypass surgery. When definitive, randomized studies become available, their data will be invaluable in defining some of the unresolved issues contained herein.

Much of the data presented may appear several times, in different series. For example, a data set may initially be used to evaluate PTCA's efficacy and complications for 50 patients. These same patients may later be included in expanded series or the patients may be included in larger studies, if the study institution reports their results to a national registry. Because of this limitation, in many tables we did not aggregate findings but rather present the results of individual studies by author, institution (or registry), and by the time period in which patients were enrolled. When reasonable, weighted averages of relevant data are presented in the text. The weighted average gives more weight to larger studies when calculating reported benefits. Studies which potentially overlap are excluded from analysis.

Chapter 2

EFFICACY

When studying the efficacy of percutaneous transluminal coronary angioplasty, the primary outcomes are relief of angina, prevention of myocardial infarction, and long term survival. Most studies report angiographic success and clinical success (defined below) in terms of the findings during and immediately following PTCA. Immediate relief of angina is usually not included among the immediate findings. It appears, however, that angiographic and clinical success are accompanied by hemodynamic and symptomatic improvement in 80-85% of patients. [23888, 21282]

Percutaneous transluminal coronary angioplasty has been recommended as an alternative to coronary artery bypass surgery in selected patients with coronary artery disease. [19146] The short term success rate (primary success) and the rate of restenosis following PTCA are the principle factors limiting the efficacy of the procedure. In this chapter, factors influencing the primary success and restenosis rates will be discussed followed by consideration of the procedure's efficacy in specific clinical settings.

Investigators report late adverse outcomes differently. [25021] The most serious problem is that most authors do not follow patients individually for a fixed amount of time, but rather report a long term outcome (e.g., recurrent angina, repeat revascularization) by stating a mean follow time and either a standard deviation or follow up time range. On the other hand, most studies specifically addressing restenosis have shown that restenosis is most likely to occur within the first six months following PTCA. The majority of patients with recurrent symptoms beyond six months (and definitely beyond one year) are more likely to have disease progression rather than restenosis.

Studies in this chapter were not excluded based on patients' year of enrollment because long term outcome in successful angioplasty patients appears related to dilation adequacy and intrinsic patient characteristics, not the success rate in any institution. This may overestimate long term adverse outcomes because, although the pathophysiology of disease progression (e.g. restenosis) has remained unchanged, medical therapy is now more sophisticated, permitting better control of recurrent disease without repeat PTCA or bypass surgery.

Coronary atherectomy (e.g., controlled removal of atherosclerotic tissue from vessel walls [26020]) has been recently introduced as an alternative to angioplasty [26020, 26021, 26022, 26023, 26024, 26025, 26026]. Initial findings in some series suggest atherectomy may reduce dissection and decrease residual narrowing in treated vessels compared to coronary angioplasty. [26021, 26025] It is plausible that atherectomy may expand the indications for percutaneous transluminal revascularization. Because atherectomy is still considered investigational, it will not be further considered in this review.

Coronary reperfusion catheters have been introduced recently as an adjunct to maintain coronary blood flow in patients awaiting coronary artery bypass surgery after failed angioplasty. [26030, 26031, 26032, 26033] Coronary reperfusion may prove to reduce the incidence of myocardial infarction and death in patients following failed angioplasty. Because definitive data are currently unavailable, coronary reperfusion is not further included in this review.

In this chapter, studies which group all patients together or do not explicitly identify indication subgroups are included in the general discussion which immediately follows. Studies specifically identifying indications are discussed in their respective sections.

RESULTS

Primary Success

The major advances contributing to the long term benefits of PTCA are those which have improved primary success. Primary angiographic success is broadly defined as revascularization of stenotic or occluded coronary arteries. Clinical success is defined as angiographic success in the absence of any major complication (i.e., myocardial infarction, emergency coronary artery bypass surgery, or death). Some authors define primary success as angiographic success whereas others refer to clinical success by the term primary success. A major problem in assessing and comparing primary success rates is the lack of standardization regarding the definition of angiographic success. Commonly employed definitions of angiographic success include: 20% stenosis reduction [4, 1123, 1543, 3415, 3658, 4255, 7072, 9034, 12565, 12685, 12859, 14992], 20% stenosis reduction and less than 50% residual stenosis [14362, 12274, 3667, 7771, 8146, 9181], 30% stenosis reduction [5593, 2116, 9805], 30% stenosis reduction and less than 50% residual stenosis [3322], 40% stenosis reduction [6745, 6757, 997, 2698], less than 40% residual stenosis [15094, 11365, 11374], less than 50% residual stenosis [5, 1072, 1260, 2659, 3184, 3187, 3190, 3193, 3196, 3202, 3664, 4147, 5347, 6352, 7534, 8866, 10297, 12037, 12571, 13585, 13603, 13795, 14917, 15277, 15430, 16033], less than 50% residual stenosis and less than 20 mmHg transtenotic gradient [6766], and less than 50% residual stenosis and less than 30 mmHg transtenotic gradient [14254, 4399]. When the patient presents with total occlusion, some have categorized any reperfusion as successful [11389, 9805]. Some investigators report angiographic success by vessel rather than by patient, further limiting comparison among studies.

Several factors have been shown to significantly affect the primary success rate. The first large series of data regarding primary success was from the initial National Heart, Lung and Blood Institute registry interim report, which reviewed results submitted from 34 centers in the United States and Europe. PTCAs in this series were performed between early 1979 to August 1980 [22778]. The initial success rate in this series (at least 20% increase in luminal diameter) was 59%. Although the extent of significant coronary artery disease was not limited by the study protocol, 80% of patients had single vessel disease and 63% of stenoses were in the left anterior descending coronary artery. Most patients in this initial registry, therefore, were optimal candidates for PTCA by current criteria. Current primary success rates for all patients exceed 90%.

The main advances resulting in improved success have been technical. Anderson [18099] and Tuzcu [22347] review the impact that these changes made in angiographic success rates. The early catheter systems, before 1982-1983, were double lumen balloon catheters with fixed, flexible guidewires at their tip. In mid-1982 a steerable catheter was introduced which contained an independent, steerable guidewire. In late 1983 a low profile dilation catheter was introduced, which permitted cardiologists to traverse lesions which would not permit passage by conventional catheters. These were major advances as 29% of PTCAs were unsuccessful in the initial NHLBI study because of inability to cross the stenosis and 12% were unsuccessful due to inability to dilate the lesion [22778]. Improvements in catheter design permitted patients with more difficult coronary anatomy to be successfully dilated using PTCA. Improvements were most dramatic for patients with right coronary artery and left circumflex artery stenoses (Table 2.1)

Table 2.1 Improvements in PTCA Primary Success Rates Over Time by Artery Dilated
(number of patients shown in parentheses)

	Initial NHLBI 1979-1980 22778	Cleveland Clinic 1980-1983 22347	Cleveland Clinic 1983-1985 22347	Cleveland Clinic 1985-1987 22347
Vessel	Non-steerable	Non-steerable	Steerable	Low profile
LAD	63%(426)	76%(111)	95%(570)	95%(654)
RCA	53%(158)	59%(39)	93%(346)	91%(418)
LCx	39%(36)	84%(18)	93%(201)	93%(320)
LAD - Left Anterior Descending		RCA - Right Coronary Artery		
LCx - Left Circumflex Artery				

A second major contributing factor to the angioplasty primary success rate is the experience of the operator performing the procedure. [5992, 19221, 20208, 20841, 21642, 22296, 23048] Hamad, *et al* observed a 91% clinical success rate among three operators performing at least 100 procedures and an 84% rate among 14 individuals performing an average of 25 procedures from May 1986 to April 1987. [5992] Complication rates in this study were 1.8% for experienced operators and 3.2% for less experienced individuals when dilating simple lesions. Corresponding rates for complex lesions were 3.1% and 7.5%, respectively. Finci observed a 93% success rate among high volume (average 14.9 PTCA/month) operators and an 85% success rate among low volume (1.3 PTCA/month) operators performing single vessel PTCA. [19221] Kelsey, *et al*, reporting on findings from the initial NHLBI registry, examined individual physician success rates for left circumflex artery PTCA and observed a 41% success rate among the first 50 patients, a 54% success rate among the next fifty, and a 75% success rate was achieved for patients after the first 100. [20208] Although overall success rates have increased since the initial NHLBI registry, this study demonstrates, as do others, that operator experience is an important component of PTCA success.

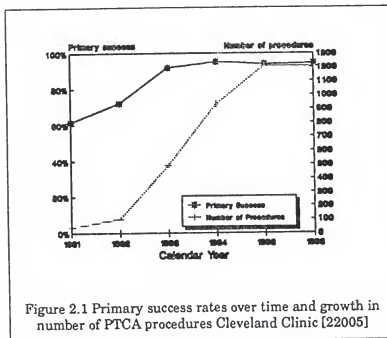
A number of studies have identified significant factors which are predictive of primary success, although agreement on which of these variables are consistently predictive of outcome varies. These factors include multiple vessel disease [1543,1861], the degree of initial stenosis [3202, 19575, 22296], lesion morphology [1543, 10258, 14521, 18804, 19128, 19575, 19995], patient age [7897, 19575, 19872], left ventricular function [19575, 19872], previous coronary artery bypass surgery [7897], gender (females lower) [1543, 7897, 18804, 19128, 19575, 19872], lesion length [1861, 10258, 19128], residual stenosis following PTCA [1861, 19128], and duration of angina or occlusion (in patients with occluded vessels) [8866, 19872, 3322].

The weighted average primary success rate was 87% for studies enrolling patients on or after 1980. (Table 2.2) [3415, 5347, 12685, 13603, 14362, 15430, 22005, 22116, 22368, 21474] The reliability of this average is weakened by the different definitions of primary success used by the investigators. Simpfordorfer, *et al*, at the Cleveland Clinic, using a definition of 20% reduction in stenosis with less than 50% residual stenosis reported annual primary success rates from 1981-1986. [22005] Primary success rates at the Cleveland Clinic for these years were 61.5% (N=39), 72% (N=100), 91.8% (N=490), 95.2% (N=930), 93.9% (N=1209), and 94.4% (N=1205), respectively. These primary success rates are also somewhat misleading because, although the data are not grouped by indication, patients

with more complex coronary artery disease and comorbid conditions are included in later years. [1861, 19146]

TABLE 2.2 - Primary Success Rates in Patients Undergoing PTCA

Author	Reference	Years	Number	Percent
Berger	1072	<1984	186	75.8%
Detre	3415	77-81	1155	61.0%
Detre	3415	85-86	1802	78.0%
Dorros	3667	79-86	752	87.5%
Finci	4396	83-86	530	87.4%
Glazier	5347	80-87	1162	87.0%
Mock	10564	77-81	2709	62.0%
Raizner	12685	80-84	518	79.5%
Sahni	13603	1985	124	91.1%
Shimizu	14362	81-82	44	81.8%
Steffenino	14992	83-85	327	86.2%
Talley	15430	1981	427	79.2%
Valentine	16123	80-83	126	73.8%
Dorros	19077	78-83	1826	91.5%
Hirzel	23058	1977	50	64.0%
Simpfendorfer	22005	1981	39	61.5%
Simpfendorfer	22005	1982	100	72.0%
Simpfendorfer	22005	1983	490	91.8%
Simpfendorfer	22005	1984	930	95.2%
Simpfendorfer	22005	1985	1209	93.9%
Simpfendorfer	22005	1986	1205	94.4%
Steffenino	22116	83-86	500	86.0%
Valentine	22368	80-86	500	89.0%
Mabin	20658	79-82	244	67.0%
Rapold	21474	80-83	268	67.5%



Restenosis and Recurrent Angina

Despite the technical advances that have improved PTCA primary success rates, the value of the procedure has been limited by restenosis (i.e., the recurrence of disease at the angioplasty site). [22928] As with primary success, different definitions for restenosis exist and different investigators report restenosis using different criteria. Commonly used criteria include: 1) increased diameter stenosis

of at least 30% at the time of follow up; 2) immediate post-PTCA stenosis of <50% increasing to $\geq 70\%$; 3) increased stenosis with severity to within 10-20% of the predilation diameter stenosis; 4) loss of at least 50% of the initial PTCA gain; 5) increased stenosis from <50% to $\geq 50\%$; and 6) at least 0.72 mm increase in stenosis. [22808, 20631, 23588] Different classes of drugs have been tried but have failed to reduce the restenosis rate, including calcium antagonists, anticoagulants, anti-platelet agents, and steroids. [21612, 1260, 26013] Recent data suggests that omega-3 fatty acids may have some benefit in preventing restenosis although the benefit of this regimen remains controversial. [20874, 26012, 16013]

In an attempt to minimize restenosis, treat inimal dissection and abrupt closure following angioplasty, intracoronary stents have recently been introduced as an adjunct to coronary angioplasty. [26004, 26005, 26006, 26007, 26008, 26009, 26010, 26011] Vogt followed for one year 95 consecutive patients in whom coronary stents were placed. [26007] Six patients died, two related to the stent. At 12 months, restenosis was observed in four patients, less than the restenosis rate in nonstented patients. Because of the investigational nature of this procedure and the lack of conclusive evidence regarding the efficacy and range of applications for intracoronary stenting, this adjunctive procedure will not be further considered in this review.

At an average follow up time of 5.6 months, Kaltenbach reported a restenosis rate of 12-17%, depending on the restenosis definition used. [20148] Similarly, at three months follow up, Luijten reported restenosis rates of 15-26% for patients with stable angina and 12-25% for patients with unstable angina at the time of PTCA, depending on the definition of restenosis. [20631]

Restenosis rates are also problematic in that restenosis, unlike recurrent angina, is an angiographically defined process. Consequently, patients must submit to repeat angiography for determination of whether or not restenosis exists. Although most patients with recurrent angina are likely to agree to restudy when indicated, asymptomatic patients are considerably less likely to agree to the procedure. [23588, 23598] Although some patients may die or be lost during the follow up period, published restenosis rates are most likely to overstate the true restenosis rate when only symptomatic and a proportion of asymptomatic patients are angiographically restudied.

Holmes, *et al*, analyzing the initial NHLBI registry data, looked at clinical symptoms and restenosis rates. [22978] Restenosis was observed in 56% of patients with definite or probable angina and in only 14% of patients who were asymptomatic at the time of angiography. Deligonul and colleagues at St. Louis University obtained one year angiographic follow up on 222 of 373 (61%) patients. [18945] Of 103 symptomatic patients, multiple restenoses occurred in 25%. The corresponding rate among 119 asymptomatic patients restudied was 3%. Of the 222 patients restudied, 17% developed a restenosis without recurrent angina.

Those studies presenting data on restenosis but not classified by specific indication, are included in table 2.3 and those addressing recurrent angina are shown in table 2.4.

TABLE 2.3 - Restenosis Rates in Patients Undergoing PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Cook	2659	82-88	205	17.6%	6 Mo
Dorros	3667	79-86	658	27.8%	31 Mo
Ernst	4147	80-85	728	23.9%	6 Mo
Glazier	5347	80-87	1011	20.0%	28 Mo
Sahni	13603	1985	113	15.0%	19 Mo
Steffenino	14992	83-85	195	33.3%	10 Mo
Valentine	16123	80-83	80	25.0%	13 Mo
Hirzel	23058	1977	32	15.6%	5 Yr
Holmes	22978	79-82	524	34.2%	1.5 Yr
Mabin	20658	79-82	100	32.0%	14 Mo
Rapold	21474	80-83	178	27.0%	14 Mo
Kober	23508	77-84	356	17.0%	4 Yr
Guiteras	23518	<1984	69	30.0%	5 Yr
Rothbaum	23178	82-86	85	30.6%	20 Mo

TABLE 2.4 - Recurrent Angina Rates in Patients Undergoing PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Berger	1072	<1983	141	12.8%	1 Yr
Cook	2659	82-88	258	25.6%	6 Mo
Dorros	3667	79-86	658	35.4%	31 Mo
Ernst	4147	80-85	1163	13.0%	24 Mo
Finci	4396	83-86	344	81.7%	12 Mo
Sahni	13603	1985	113	15.0%	19 Mo
Shimizu	14362	81-82	37	16.2%	7 Mo
Steffenino	14992	83-85	195	17.4%	10 Mo
Talley	15430	1981	338	15.4%	5 Yr
Kent	22778	77-80	65	17.0%	1 Yr
Mabin	20658	79-82	149	26.0%	14 Mo
Guiteras	23518	<1984	67	33.0%	5 Yr
Corbelli	23088	80-82	106	29.0%	9 Mo

Rose and Pepine have reviewed restenosis following PTCA; the findings are presented in table 2.5. [21612]

Other Long Term Events

Long term myocardial infarction, repeat PTCA, late coronary artery bypass surgery and long term mortality are addressed in tables 2.7 to 2.10, respectively.

Detre and colleagues reported one year differences in overall (in hospital and late) adverse events between the initial NHLBI PTCA registry (1977-1981) and the follow up registry (1985-1986). [18984] The risk of untoward events in the new vs old registry, with the exception of repeat PTCA, declined once the data were adjusted for comorbidities at the time of PTCA (age ≥ 65 , unstable angina, multivessel disease, ejection fraction $< 50\%$, history of myocardial infarction, coronary artery bypass graft surgery, diabetes mellitus, hypertension, and congestive heart failure. (Table 2.10)

Table 2.5 - Patient, angiographic, procedural and post-angioplasty factors associated with increased risk of restenosis [21612]

Association with increased restenosis risk	Often	Occasionally	None
Patient	Male Sex Diabetes Variant angina New onset/short duration angina	Unstable angina Anginal class No previous MI Cholesterol	Age Hypertension
Angiographic	Severe stenoses Proximal LAD lesions Spasm Aorto-SVG stenoses Body of SVG stenoses Branch point stenoses Chronic total occlusion	Eccentric stenoses	Stenoses length Distal graft-artery anastomosis Multivessel disease Left ventricular function
Procedural	High pre-PTCA gradient High final gradient Severe residual Absence of intimal tear	Low balloon/artery diameter Inflation duration	Number of inflations Inflation pressure
Post-PTCA		Smoking	Calcium antagonists Warfarin

TABLE 2.6 - Long Term Myocardial Infarction Rates in Patients Undergoing PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Berger	1072	<1983	141	4.3%	1 Yr
Ernst	4147	80-85	1163	0.9%	2 Yr
Mock	10564	77-81	1680	2.8%	1 Yr
Sahni	13603	1985	113	6.2%	19 Mo
Talley	15430	1981	338	7.1%	5 Yr
Detre	18984	85-86	1409	2.6%	1 Yr
Hirzel	23058	1977	23	0.0%	5 Yr
Guiteras	23518	<1984	67	2.0%	5 Yr
Mabin	20658	79-82	149	3.4%	14 Mo
Corbelli	23088	80-82	106	5.0%	9 Mo

TABLE 2.7 - Long Term Repeat PTCA Rates in Patients Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Ernst	4147	80-85	1163	8.2%	2 Yr
Mock	10564	77-81	1680	14.8%	1 Yr
Steffenino	14992	83-85	195	26.7%	10 Mo
Detre	18984	85-86	1409	20.7%	1 Yr
Kent	22778	77-80	65	5.0%	1 Yr
Guiteras	23518	<1984	67	8.0%	5 Yr
Corbelli	23088	80-82	106	8.0%	9 Mo

TABLE 2.8 - Long Term Coronary Artery Bypass Graft Surgery Rates in Patients Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Berger	1072	<1983	141	5.0%	1 Yr
Ernst	4147	80-85	1163	5.0%	2 Yr
Mock	10564	77-81	1680	11.6%	1 Yr
Steffenino	14992	83-85	195	4.6%	10 Mo
Detre	18984	85-86	1409	6.4%	1 Yr
Hirzel	23058	1977	50	6.0%	5 Yr
Kent	22778	77-80	65	6.0%	1 Yr
Guiteras	23518	<1984	67	16.0%	5 Yr
Corbelli	23088	80-82	106	8.0%	9 Mo

TABLE 2.9 - Long Term Mortality Rates in Patients Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
Ernst	4147	80-85	1163	1.4%	2 Yr
Mock	10564	77-81	1680	1.4%	1 Yr
Sahni	13603	1985	113	4.4%	19 Mo
Talley	15430	1981	338	4.4%	5 Yr
Detre	18984	85-86	1409	1.9%	1 Yr
Guiteras	23518	<1984	67	8.0%	5 Yr
Corbelli	23088	80-82	106	0.9%	9 Mo

Gender and Efficacy

The early NHLBI registry results demonstrated a lower angiographic and clinical success rate in women. [18807] Long term follow up (average 18 months, at least 1 year) showed a lower restenosis rate, less frequent need for revascularization, and better cumulative survival among women with successful PTCA.

McEniery and colleagues later reported on their Cleveland Clinic experience. In this series of 969 women and 2727 men (1980-1986), the primary success rate was 93% for women and 93.5% for men. [10126] At 20 months, no significant differences were found between men and women with respect to myocardial infarction, repeat angioplasty, late coronary artery bypass surgery, or follow up catheterization rates. More men (60% vs 51%), however, had a follow up exercise stress test whereas more women (21% vs 13%) were hospitalized during the follow up period for chest pain.

Table 2.10 Comparison of Long Term Follow Up Between the Initial National Heart Lung and Blood Institute Registry (1977-1981) and the Subsequent Registry (1985-1986) [18984]

Event	One Year Rate (%)		Adjusted Risk for New vs Old	90% Confidence Interval
	New	Old		
Death	3.2	2.7	0.65	0.42, 0.98
MI ¹	7.2	9.3	0.59	0.46, 0.76
Death or MI ¹	9.6	10.6	0.63	0.50, 0.79
CABG	13.2	37.2	0.25	0.21, 0.30
Repeat PTCA	18.5	11.9	1.50	1.23, 1.82

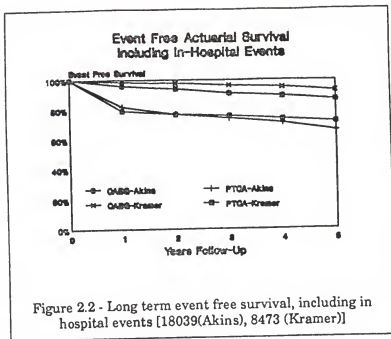
1. MI - Myocardial Infarction

Angioplasty and Bypass Surgery

Although angioplasty and coronary artery bypass surgery represent alternatives for patients with coronary artery disease, many of whom are refractory to medical therapy, randomized, controlled trial results are not yet available which directly compare the efficacy of these two treatment modalities. Studies currently underway to address this issue include the Emory Angioplasty Surgery Trial (EAST), Bypass Angioplasty Revascularization Investigation (BARI), Randomized Intervention in the Treatment of Angina (RITA), Coronary Artery Bypass Revascularization Investigation (CABRI), and the German Angioplasty Bypass Investigation (GABI). [17] In the absence of data from these randomized trials, some investigators have used other study designs to evaluate these two procedures, all acknowledging that these trials are essential to completely answer the question of which approach is best.

Akins and colleagues compared CABG with PTCA using a retrospective historical cohort design. [18039] Long term freedom from myocardial infarction, including in hospital events was 98% and 93% (1 year), 97% and 91% (3 years), and 95% and 88% (5 years), for coronary artery bypass surgery and angioplasty, respectively. Long term freedom from coronary artery bypass surgery (repeat CABG in the case of CABG patients), including in hospital events was 100% and 86% (1 year), 100% and 83% (3 years), and 99% and 85% (5 years), for coronary artery bypass surgery and angioplasty, respectively. Long term freedom from subsequent angioplasty (repeat PTCA in the case of PTCA patients), including in hospital events was 100% and 86% (1 year), 100% and 83% (3 years), and 99.5% and 75% (5 years), for coronary artery bypass surgery and angioplasty, respectively. Nevertheless, long term survival, including in hospital events was 98% and 98% (1 year), 95% and 98% (3 years), and 92% and 96% (5 years), for coronary artery bypass surgery and angioplasty, respectively. The differences between these groups, however, using stepwise Cox regression analysis, could be accounted for by age and ejection fraction at the time of the procedure. Once these two factors were accounted for, the treatment group (PTCA or CABG) was no longer significant as a factor influencing survival.

Kramer, *et al* examined long term survival, comparing CABG and angioplasty. [8473] They acknowledged that angioplasty patients had shorter hospitalization, less intervention, and decreased expense however, the postprocedural event free survival was significantly different, the surgical patients doing better than the angioplasty patients. They concluded "It may be that the higher cost and longer initial hospitalization required for CABG are



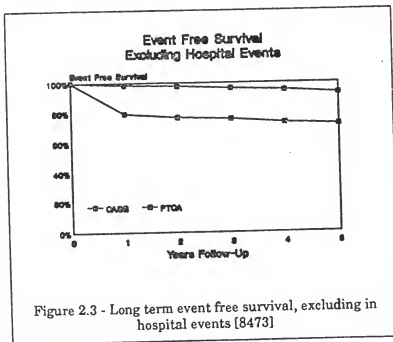
justified by superior long-term results". Long term follow up for CABG and PTCA are shown in figures 2.2 (including in hospital events) and 2.3 (post discharge events).

Hochberg and colleagues pointed out that at three years, there was not a significant mortality difference between PTCA and CABG patients (7% vs 3%), although the number of patients who were alive with significant angina (New York Heart Association Class III or IV) was significantly higher among PTCA treated patients. [6670]

Furthermore, 19% of PTCA patients required subsequent CABG whereas only 2% of CABG patients needed PTCA during the three year follow up period. They conclude "We no longer accept the argument that *if all things are equal* angioplasty is preferable to bypass grafting because it causes less discomfort to the patient, decreases the duration of hospitalization, and ultimately is cheaper for the patient and the health care economy. *All things are not equal*. These data revealing 3-year follow-up of matched patients undergoing angioplasty or bypass prove this point."

Chronic Stable Angina

Patients with chronic stable angina have always been considered reasonable candidates for PTCA. In the initial NHLBI registry (1977-1982), chronic stable angina accounted for 666 of 1939 (34%) patients registered. [18276] The weighted average primary success rate for patients with chronic stable angina was 85.3%. [7072, 7534, 12037, 23048] As with other indications, the complexity of patients with chronic stable angina has increased over the last decade (e.g., multivessel disease, relatively high risk anatomy).



The restenosis rate among chronic stable angina patients in the initial NHLBI registry was 30.4% (N=148); patients were followed an average of 18 months. Recurrent angina was present in 14.9% of 346 patients studied during the same time period. [18276] As discussed previously, restenosis rates are likely overstated because patients not receiving angiographic reevaluation are excluded. If one assumes the remaining 198 patients not reangiographed were asymptomatic with a 14% restenosis rate, the restenosis rate for all patients followed for 18 months was 21% ((28+45)/346).

Among patients treated for chronic stable angina, studies of long term restenosis, recurrent angina, repeat PTCA, subsequent coronary artery bypass surgery, late myocardial infarction and death are shown in table 2.11.

TABLE 2.11 - Long Term Follow Up Rates in Chronic Stable Angina Patients Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
<u>RESTENOSIS</u>					
Ischinger	7072	84-86	58	29.3%	11 Mo ¹
Bentivoglio	18276	77-81	148	30.4%	18 Mo
Luijten	20631	84-85	206	26.7%	3 Mo ¹
<u>RECURRENT ANGINA</u>					
Bentivoglio	18276	77-81	346	14.9%	18 Mo
Simpfendorfer	23048	81-86	124	21.0%	29 Mo
Luijten	20631	84-85	206	22.3%	3 Mo ¹
<u>REPEAT PTCA</u>					
Ischinger	7072	84-86	58	19.0%	11 Mo ¹
Bentivoglio	18276	77-81	666	15.6%	18 Mo
Simpfendorfer	23048	81-86	111	21.0%	29 Mo
<u>BYPASS SURGERY</u>					
Kamp	7534	80-85	420	13.2%	6 Mo
Bentivoglio	18276	77-81	666	7.5%	18 Mo
Simpfendorfer	23048	81-86	111	13.0%	29 Mo
<u>MYOCARDIAL INFARCTION</u>					
Kamp	7534	80-85	420	6.0%	6 Mo
Bentivoglio	18276	77-81	666	2.3%	18 Mo
Simpfendorfer	23048	81-86	111	2.4%	29 Mo
<u>MORTALITY</u>					
Kamp	7534	80-85	420	2.0%	1 Yr
Bentivoglio	18276	77-81	346	0.6%	18 Mo
Simpfendorfer	23048	81-86	111	10.8%	29 Mo

1. Follow up less than six months

Unstable Angina

Unstable angina accounted for the majority (66% of 1,939) of patients enrolled in the initial NHLBI registry. [18276] Because these patients are at increased risk of myocardial infarction, revascularization by PTCA offers an alternative to surgery.

The primary success rate for unstable angina patients in the initial NHLBI registry (1977-1981) was 64.6%, comparing favorably with the 65.6% success rate among patients with chronic stable angina. In later studies the weighted average primary success rate was 88.8%. [5593, 7534, 12037, 12565, 13585, 23048, 22122].

Kamp, *et al* observed a 14.2%, non-fatal myocardial infarction rate among unstable patients with long term follow up compared with 8.3% of patients studied for the three year period with chronic stable angina. [7534] These myocardial infarction rates are higher than

those reported by Simpfordorfer from the Cleveland Clinic, who reported myocardial infarction rates of 2.4% and 1.4%, for patients at least 70 years old with stable and unstable angina, respectively, followed for an average of 29 months. [23048].

Among patients treated for unstable angina, studies of long term restenosis, recurrent angina, repeat PTCA, subsequent coronary artery bypass surgery, late myocardial infarction and death are shown in table 2.12.

TABLE 2.12 - Long Term Follow Up Rates in Unstable Angina Patients Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
<u>RESTENOSIS</u>					
de Feyter	3184	83-84	136	26.5%	6 Mo
Quigley	12565	82-84	20	20.0%	14 Mo ¹
Bentivoglio	18276	77-81	184	35.9%	18 Mo
Steffenino	22122	83-85	80	26.3%	10 Mo ¹
Luijten	20631	84-85	133	24.8%	3 Mo ¹
<u>RECURRENT ANGINA</u>					
de Feyter	3184	83-84	136	18.4%	6 Mo
de Feyter	3190	83-85	47	27.7%	6 Mo
Gottlieb	5593	Unstated	37	13.5%	16 Mo
Quigley	12565	82-84	20	35.0%	14 Mo ¹
Safian	13585	81-85	58	41.4%	17 Mo
Bentivoglio	18276	77-81	641	6.8%	18 Mo
Simpfendorfer	23048	81-86	212	25.0%	29 Mo
Steffenino	22122	83-85	80	7.0%	10 Mo ¹
<u>REPEAT PTCA</u>					
de Feyter	3184	83-84	136	9.6%	6 Mo
de Feyter	3190	83-85	47	6.4%	6 Mo
Safian	13585	81-85	58	5.2%	17 Mo
Bentivoglio	18276	77-81	641	15.4%	18 Mo
Simpfendorfer	23048	81-86	197	22.0%	29 Mo
Steffenino	22122	83-85	57	22.8%	10 Mo ¹
<u>BYPASS SURGERY</u>					
de Feyter	3184	83-84	136	5.9%	6 Mo
de Feyter	3190	83-85	47	12.8%	6 Mo
Kamp	7534	80-85	141	20.8%	1 Yr
Safian	13585	81-85	58	29.3%	17 Mo
Bentivoglio	18276	77-81	641	13.4%	18 Mo
Simpfendorfer	23048	81-86	197	11.0%	29 Mo
Steffenino	22122	83-85	57	7.0%	10 Mo ¹
<u>MYOCARDIAL INFARCTION</u>					
de Feyter	3184	83-84	136	0.7%	6 Mo
de Feyter	3190	83-85	47	2.1%	6 Mo
Kamp	7534	80-85	191	14.2%	1 Yr
Quigley	12565	82-84	20	0.0%	14 Mo ¹
Simpfendorfer	23048	81-86	197	1.4%	29 Mo
Steffenino	22122	83-85	57	1.8%	10 Mo ¹
<u>MORTALITY</u>					
de Feyter	3184	83-84	136	0.7%	6 Mo
de Feyter	3190	83-85	47	2.1%	6 Mo
Kamp	7534	80-85	191	3.0%	1 Yr
Quigley	12565	82-84	20	0.0%	14 Mo ¹
Bentivoglio	18276	77-81	641	1.2%	18 Mo
Simpfendorfer	23048	81-86	197	6.6%	29 Mo

1. Follow up less than six months

Variant Angina

Only a few studies have specifically addressed the issue of patients with atherosclerotic disease superimposed on variant angina. The average primary success rate among the 124 patients reported was 93.6%. [1123, 9034] Studies suggest that the restenosis rate among patients with variant angina is higher when compared with individuals without coexisting vasospasm. [1123, 9031, 9034] Calcium channel antagonists appear to offer variant angina patients relief from early return of angina.

Total Occlusions

Angioplasty is less successful among patients with chronic total occlusion. Stone, *et al*, reported a series of 905 angioplasties from total occlusion, with a primary success rate of 72%, compared to a 96% primary success rate in patients without total occlusion. [23408] Multivariate analysis showed only bridging collateral vessels (*e.g.* enlarged vasa vasorum) (18% vs 85%) and abrupt occlusion (59% vs 88%) to be associated with decreased success. In this study, age, gender, previous coronary artery bypass surgery, lesion location, ejection fraction, functional vs total occlusion and nonbridging collaterals were unrelated to procedural success. LaVeau and colleagues reported a 70% success rate for chronic total occlusion. [8866] This study found success to be unrelated to clinical or angiographic findings (tortuosity, length, location, collaterals, prior myocardial infarction, calcification, extent of disease). Among two other studies specifically addressing chronic total occlusion, the primary success rate was 52.9%. [4396, 13582]. Long term follow up was unavailable in those studies which specifically examined patients with chronic total occlusion. [4396, 13582, 19044]

Acute Myocardial Infarction

Angioplasty treatment options for patients with acute myocardial infarction are discussed in Chapter 3. The discussion which follows separates patients into two broad groups, those who undergo direct PTCA and those who receive thrombolytic therapy before angioplasty.

Without Thrombolysis

The average primary success rate among acute myocardial infarction patients undergoing coronary angioplasty is 91.2% [2116, 4396, 6757, 11374, 15277] Limited information is available regarding long term follow up on these patients. Flaker, *et al* at the University of Missouri observed restenosis in 20 of 73 (34%) patients angiographically restudied 7.2 days following successful PTCA. Among 98 patients followed for an average of 20 months by Suryapranata, 31 (32%) experienced recurrent angina. [15277] Over the same time period, 5.1% underwent coronary artery bypass surgery and 18.4% repeat PTCA while 5.1% experienced a myocardial infarction. [15277] The one year mortality rate following direct PTCA, reported by the Mid America Heart Institute, was 5%. [11374]

With Thrombolysis

Several studies have examined the primary success rates for PTCA patients following thrombolytic therapy. These studies divide patients into those receiving immediate angioplasty and those receiving delayed angioplasty, when indicated. The primary success rate for all patients receiving thrombolytic therapy is 85.0%. [5008, 12151, 14917, 22998, 22738] The average primary success rate for patients receiving immediate and delayed PTCA are 80.7% and 91.0%, respectively. [22998, 22738]

The Thrombolysis and Angioplasty in Myocardial Infarction (TAMI I) trial included 86 patients for whom coronary angioplasty was attempted due to persistent coronary artery occlusion after intravenous tissue type plasminogen activator (TPA). Seventy-three percent were successfully reperfused (<50% residual stenosis), 16% had some reperfusion (>50% stenosis), and PTCA failed to reopen the occlusion in 11%. Among successful coronary angioplasty patients, 29% experienced a reocclusion while still hospitalized, despite the use of anticoagulants and antiplatelet medications. [26002]

Abbott-Smith, *et al*, compared patients requiring "rescue" (*i.e.*, reperfusion by PTCA after failed thrombolysis) angioplasty with patients for whom thrombolytic therapy achieved reperfusion. [27002] Although patients requiring rescue PTCA had a lower ejection fraction (acute and one week later) and more frequent reocclusion (11% vs 21%), the in-hospital and long-term (median follow up 20 months) mortality rates were similar between the two groups.

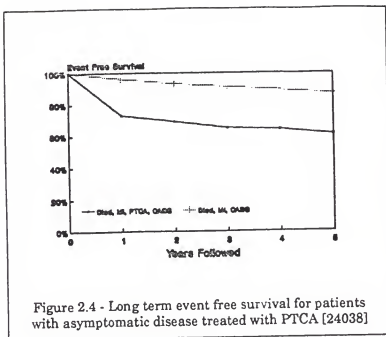
Simonton, *et al*, reported thirty week follow up of patients with emergent coronary angioplasty for myocardial infarction compared to patients undergoing elective angioplasty. [26002] In this study, the in-hospital reocclusion rate was 13% for emergent PTCA compared with 2% for elective coronary angioplasty patients. At follow up, myocardial infarction patients were more likely to be asymptomatic (79% vs 55%) and were less likely to demonstrate restenosis (19% vs 35%).

Cardiogenic Shock

Lee and colleagues evaluated the benefit of angioplasty in patients with cardiogenic shock, comparing University of Michigan patients who received angioplasty and conventional therapy (N=24) with those only receiving conventional therapy (N=59). [26003] Thirty day survival was 50% in the former group and only 17% in the latter. Success in angioplasty patients was, as expected, contingent upon successful reperfusion.

Asymptomatic Patients

Controversy remains regarding coronary angioplasty for asymptomatic patients whose only evidence of ischemia is that found on laboratory evaluation (*e.g.*, exercise stress testing). For these patients, primary success rates are excellent, averaging 91.8%. [4399, 23478] Tuzco and colleagues from the Cleveland clinic performed PTCA on 34 asymptomatic patients, of which 31 were successful. [23478] Patients were followed for an average of 36 months after successful PTCA. Twenty-nine of 31 patients had a normal or improved exercise stress test; repeat angiography was performed in 77%. Restenosis was observed in seven of 24 patients (29%). In this small study, overall long term survival at three years was 97% and event-free survival (freedom from myocardial infarction, repeat PTCA, coronary artery bypass surgery, and death) at three years was 87%.



Anderson and associates from Emory University followed 114 patients following PTCA for asymptomatic disease. [24038] This represented 1.7% of their angioplasty patients from 1980-1987. The primary success rate was 87%. Long term event-free survival (freedom from death, myocardial infarction, coronary artery bypass surgery, or repeat PTCA) was 73%, 69%, 65%, 64%, and 61% at one through five years, respectively. Excluding repeat angioplasty as an "event" corresponding event-free survival was 96%, 93%, 91%, 89% and 87%. (Figure 2.4) There were no deaths during the five year follow up period.

Elderly Patients

Although initial PTCA guidelines suggested the procedure be performed only in patients less than 60 years of age [18276], it soon became clear that older patients may benefit from coronary angioplasty. The 89.9% average primary success rate for older patients (i.e., studies including only patients at least 60 years old) is similar to that of their younger counterparts. [2659, 8146, 12685, 16084, 23048, 22908, 19974] Hartzler and colleagues from the Mid America Heart Institute separately examined their 75 patients who were over 80 years old at the time of PTCA. [22908] The primary success rate for all 1038 patients at least 70 years old was 94%; for those between 80 and 92 years, the primary success rate was 89%.

Simpfendorfer, *et al* reported a 94% overall long term survival at 1 year, decreasing to 92% at 2 years, and 91% at 3 and 4 years (N=336). [23048] Long term event free survival, excluding repeat PTCA as an event, was 84% at 1 year, 80% at 2 years, 76% at 3 years, and 74% at 4 years. (Figure 2.5) Hartzler, looking at their patients at least 80 years old, observed a 77% survival rate at 1 and 2 years. [22908]

Among elderly patients treated with PTCA, studies of long term restenosis, recurrent angina, repeat PTCA, subsequent coronary artery bypass surgery, late myocardial infarction and death are shown in table 2.13.

Younger Patients

Only one series specifically examined PTCA in patients under 36 years old. A patient based primary success rate was not reported in this study; however, 242 of 253 lesions in which angioplasty was attempted were successfully dilated. When late death, myocardial infarction and coronary artery bypass surgery are considered as adverse events, the three year survival and event free survival were 98.4% and 93.0%, respectively. [15094] Among the 69 patients followed for an average of 32 months, there was one late death (1.4%), four non-fatal myocardial infarctions (5.8%), and seven coronary artery bypass surgeries (10.1%). At follow up 73.5% were asymptomatic while the remaining 26.5% experienced at least functional class II angina.

TABLE 2.13 - Long Term Follow Up Rates in Elderly PTCA Patients

Author	Reference	Years	Number	Percent	Follow-Up
<u>RESTENOSIS</u>					
Cook	2659	82-88	22	22.7%	6 Mo ^B
Kitazume	8146	83-86	95	36.8%	6 Mo ^B
Raizner	12685	80-84	76	9.2%	22 Mo ^{1,B}
Urban	16084	83-86	47	38.3%	4 Mo ^{1,B}
Bentivoglio	18276	77-81	50	40.0%	18 Mo ^A
<u>RECURRENT ANGINA</u>					
Raizner	12685	80-84	76	23.7%	22 Mo ^{1,B}
Bentivoglio	18276	77-81	196	6.9%	18 Mo ^A
Simpfendorfer	23048	81-86	308	23.7%	29 Mo ^C
Dorros	19068	78-84	77	18.2%	23 Mo ^C
<u>REPEAT PTCA</u>					
Mock	10564	77-81	196	9.9%	1 Yr ^B
Bentivoglio	18276	77-81	196	11.7%	18 Mo ^A
Dorros	19068	78-84	77	18.2%	23 Mo ^C
Simpfendorfer	23048	81-86	308	21.8%	29 Mo ^C
Imburgia	19974	85-87	26	15.4%	15 Mo ^{1,D}
<u>BYPASS SURGERY</u>					
Mock	10564	77-81	196	11.4%	1 Yr ^B
Urban	16084	83-86	36	13.9%	4 Mo ^{1,B}
Bentivoglio	18276	77-81	196	11.7%	18 Mo ^A
Dorros	19068	78-84	77	1.3%	23 Mo ^C
Simpfendorfer	23048	81-86	308	11.7%	29 Mo ^C
Imburgia	19974	85-87	26	11.5%	15 Mo ^{1,D}
<u>MYOCARDIAL INFARCTION</u>					
Mock	10564	77-81	196	2.5%	1 Yr ^B
Bentivoglio	18276	77-81	196	4.1%	18 Mo ^A
Dorros	19068	78-84	77	2.6%	23 Mo ^C
Simpfendorfer	23048	81-86	308	1.6%	29 Mo ^C
<u>MORTALITY</u>					
Mock	10564	77-81	196	1.9%	1 Yr ^B
Raizner	12685	80-84	76	2.6%	22 Mo ^{1,B}
Urban	16084	83-86	36	2.8%	4 Mo ^B
Dorros	19068	78-84	77	3.9%	23 Mo ^C
Simpfendorfer	23048	81-86	308	8.1%	29 Mo ^C
Imburgia	19974	85-87	26	11.5%	15 Mo ^{1,D}

1. Follow up less than six months

A. ≥ 60 years, B. >65 years, C. ≥ 70 years, D. ≥ 75 years**Number of Vessels Involved****Single Vessel**

Patients with single vessel disease were the first for whom percutaneous transluminal coronary angioplasty was recommended. Bredlau, *et al*, from Emory University reported a 92% primary success rate among their 2835 patients with single vessel disease between 1980 and 1984. [1543] Gruentzig reported on the long term follow up of his initial 169 patients who received PTCA in Zurich, Switzerland. [23018] The survival among all 133 technically successful patients at six years was 93%. Cardiac survival (*i.e.*, excluding

patients who die from non cardiac causes) at six years was 98% among patients with single vessel disease.

Detre and participants in the NHLBI's second PTCA registry reported one year follow up on patients receiving PTCA between 1985 and 1986. Seven hundred six patients with single vessel disease were recorded by the registry. Adverse events at one year included 9 deaths (1.3%), 12 myocardial infarctions (1.7%), 39 coronary artery bypass surgeries (5.5%), and 140 repeat angioplasties (19.8%). [18984] The data in this registry showed that untoward events were less frequent among patients with single vessel disease when compared to those with disease involving more than one vessel.

Multiple Vessel

The number of patients with multivessel disease who undergo PTCA has increased dramatically. In the initial NHLBI registry (N=1155), 18% had double vessel disease and 8% triple vessel stenosis. Among patients from the same institutions reporting to the second NHLBI registry (N=1802) 32% had 2-vessel disease and 22% 3-vessel disease. [3415] The weighted average primary success rate among patients with multivessel disease is 92.7%. [1543, 4396, 7771, 18945, 22908, 20445, 23078] Variations in the definition of primary success for multivessel disease are subject not only the definitional problems already discussed but also to different definitions of success with respect to the number of vessels dilated. Some define successful as dilation of the most critical stenosis while other require success among all vessels attempted.

The Mid America Heart Institute reported a 90% survival rate at four years among patients without high risk conditions (left main/left main equivalent disease, ejection fraction $\leq 40\%$, age ≥ 70 years), [22908] Among patients treated with PTCA for multivessel disease, studies of long term restenosis, recurrent angina, repeat PTCA, subsequent coronary artery bypass surgery, late myocardial infarction and death are shown in table 2.14.

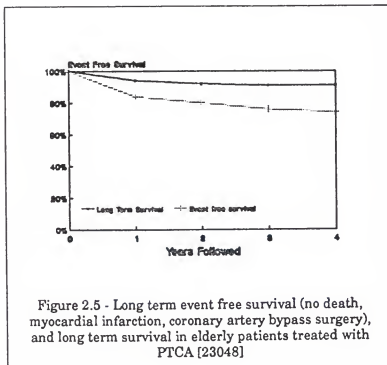


TABLE 2.14 - Long Term Follow Up Rates in Patients with Multivessel Disease Following PTCA

Author	Reference	Years	Number	Percent	Follow-Up
<u>RESTENOSIS</u>					
Dorros	19077	78-83	285	20.4%	7 Mo
Finci	19227	83-86	59	42.4%	12 Mo
Lambert	20445	81-86	135	31.1%	6 Mo
Mata	23098	80-84	74	35.1%	6 Mo
<u>RECURRENT ANGINA</u>					
Finci	4396	83-86	87	35.6%	12 Mo
Cowley	18810	79-84	44	34.1%	1 Yr
DiSciascio	19041	79-87	50	34.0%	6 Mo
Vlietstra	22434	<1983	55	27.3%	6 Mo
Lambert	20445	81-86	114	28.9%	6 Mo
Gruentzig	23018	77-80	52	32.7%	6.5 Yr
<u>REPEAT PTCA</u>					
Finci	4396	83-86	87	18.4%	1 Yr
Cowley	18810	79-84	44	20.5%	1 Yr
Detre	18984	85-86	702	21.7%	1 Yr
DiSciascio	19041	79-87	50	30.0%	6 Mo
Finci	19227	83-86	59	25.4%	12 Mo
Lambert	20445	81-86	114	18.4%	6 Mo
Gruentzig	23018	77-80	52	17.3%	6.5 Yr
<u>BYPASS SURGERY</u>					
Finci	4396	83-86	87	8.0%	1 Yr
Cowley	18810	79-84	44	18.2%	1 Yr
Detre	18984	85-86	702	8.1%	1 Yr
DiSciascio	19041	79-87	50	4.0%	6 Mo
Dorros	19077	78-83	285	6.0%	7 Mo
Finci	19227	83-86	59	11.9%	1 Yr
Vlietstra	22434	<1983	55	10.9%	6 Mo
Lambert	20445	81-86	114	1.8%	6 Mo
Gruentzig	23018	77-80	52	13.5%	6.5 Yr
<u>MYOCARDIAL INFARCTION</u>					
Detre	18984	85-86	702	3.4%	6 Mo
DiSciascio	19041	79-87	50	4.0%	6 Mo
Lambert	20445	81-86	114	1.8%	6 Mo
<u>MORTALITY</u>					
Detre	18984	85-86	702	2.6%	1 Yr
DiSciascio	19041	79-87	50	4.0%	6 Mo
Dorros	19077	78-83	285	0.0%	7 Mo
Hartzler	22908	80-87	3612	10.0%	4 Yr
Lambert	20445	81-86	114	0.9%	6 Mo
Gruentzig	23018	77-80	52	11.5%	6.5 Yr

1. Follow up less than six months

Bell and colleagues from the Mayo Clinic examined 867 patients after successful coronary angioplasty (defined as $\geq 40\%$ reduction of the luminal diameter of at least one stenosis without complications requiring coronary artery bypass surgery). [25021] They questioned whether complete revascularization (successful dilation of all stenoses $\geq 70\%$) was an important determinant of cardiac event free survival. In this study, primary success

rates (as defined above) were 84% and 83% for two and three vessel disease, respectively. Complete revascularization, however, was achieved in 51% of 540 patients with two vessel disease and only 25% of 327 patients with three vessel disease. After adjusting for baseline characteristics (e.g. age, gender, diabetes, hypertension, anginal class, unstable angina, prior myocardial infarction, congestive heart failure, PTCA within the last 24 hours, ejection fraction and total occlusion), no significant predictive value of completeness of revascularization was found for risk of death, myocardial infarction, coronary artery bypass surgery, return of severe angina, repeat or PTCA. The results of the study are shown in figure 2.6. This study suggests, therefore, that although complete vs. incomplete revascularization appears important for long term event free survival, baseline patient characteristics possibly account for the perceived differences.

Triple Vessel Disease

Although at first triple vessel coronary artery disease (*i.e.*, left anterior descending, left circumflex, right coronary artery) was considered a contraindication to PTCA, patients with triple vessel disease are now treated with angioplasty. Deligonul reported a clinical success rate of 88% (107/121) for patient with triple vessel disease when successful dilation of only the critical lesion was required for success. [18945] Complete revascularization was achieved in 26% of triple vessel disease patients compared with 34% of those with two vessel disease. Among 100 patients with three vessel disease followed at least one year, 13 required repeat PTCA, 15 required subsequent CABG, five had an acute myocardial infarction, and five died. Patients with incomplete revascularization by PTCA were significantly more likely to require CABG.

Among 50 patients with triple vessel disease at the Medical College of Virginia, all experienced symptomatic relief from angina following PTCA (*i.e.*, improvement of at least two functional classes or achievement of asymptomatic status). [19041] Survival was 96% at one and two years. Freedom from death, myocardial infarction, or bypass surgery was 90% at one and two years, dropping to 80% at three years.

Repeat PTCA

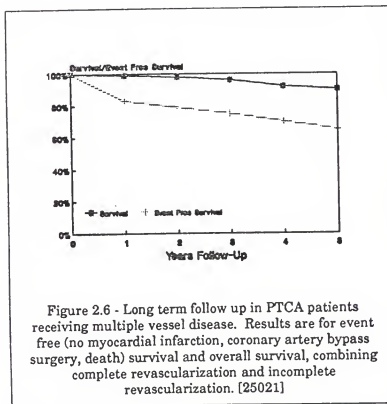
The rate of repeat PTCA as a treatment for recurrent anginal symptoms has increased over the last decade, as demonstrated by the data from the initial and follow up NHLBI registries presented in the introductory part of this chapter. As demonstrated in table 2.14, primary success rates for patients undergoing repeat PTCA are similar to those not having previous angioplasty. The data suggests an average primary success rate of 89.7% for patients undergoing repeat PTCA. [2659, 4396, 12571, 23578, 23608]. Some investigators repeatedly used angioplasty to treat recurrent disease. [3667, 5347, 13585, 14992, 21474] The likelihood of primary success does not appear to decrease with repeated dilations. Furthermore, the long term success following repeat PTCA appears to be independent of the number of procedures, as demonstrated by Glazier, *et al*, some of whose patients received five angioplasties for recurrent disease. [5349]

TABLE 2.14 Primary success, complication, and restenosis rates for patients with repeat PTCA.

Author	Paper	Year	PTCA Number	N	Primary Success	Major Complic	Restenosis
Dorros	3667	1988	2	171	94.7%	2.3%	
Dorros	3667	1988	3	28	85.7%	0.0%	
Finci	4396	1987	≥2	70	90.0%	2.9%	14.3%
Glazier	5349	1989	2	196	92.3%	3.1%	24.0%
Glazier	5349	1989	3	41	92.7%	4.9%	31.7%
Glazier	5349	1989	4	8	100.0%	0.0%	50.0%
Glazier	5349	1989	5	2	100.0%	0.0%	
Quigley	12571	1989	2	117	97.4%	0.9%	27.4%
Safian	13585	1987	2	17	88.2%	5.9%	
Safian	13585	1987	3	3	66.7%		
Steffenino	14992	1987	2	52	92.3%	1.9%	39.3%
Steffenino	14992	1987	3	5	100.0%	0.0%	
Rapold	21474	1987	2	66	90.9%	4.5%	30.3%
Rapold	21474	1987	3	9	88.9%		
Alfonso	23578	1990	2	76	92.1%	2.6%	
Kober	23508	1989	2	47	89.4%		17.0%

N=patients studied, PTCA Number=repeat procedure number

Left Main Disease



O'Keefe and colleagues provide survival and event free survival data on patients with protected (at least one patent bypass graft to the left coronary circulation) and unprotected left main PTCA patients. [11365] For patients with unprotected left main disease, a 50%, 45% and 38% survival rate was observed at 1, 2 and three years, respectively. Corresponding rates for patients with protected left main disease at the time of angioplasty were 93%, 90%, and 90%. Over the same time period, event free survival (freedom from myocardial infarction, coronary artery bypass surgery and death) was 85%, 78% and 78% for patients with protected left

main disease and 35%, 25% and 18% for those with unprotected disease. In the two elective groups, the incidence of late myocardial infarction and repeat PTCA were similar but late coronary artery bypass surgery was required significantly more often in the unprotected group (10% vs 23%). Among patients undergoing emergency left main PTCA for evolving acute myocardial infarction, three (30%) had long term survival but all required coronary artery bypass graft surgery.

Post Coronary Artery Bypass Surgery

The weighted average primary success rate for patients requiring dilation of previous coronary artery bypass grafts is 88.1%. [9856, 12274, 22798, 23388, 23658, 23668]. Kussmaul reviewed the literature on angioplasty of vein graft stenoses and concluded that the likelihood of restenosis following vein graft angioplasty appears higher than in patients undergoing native vessel angioplasty. [20415] The following evidence table also suggests that restenosis is most common in the proximal anastomotic site, lower in the body of the vein graft, and lowest at the distal anastomosis. (table 2.15)

TABLE 2.15 Restenosis rates by vessel location in previous coronary artery bypass grafts

Author	Reference	Mean Restudy Interval	Number restenosed/number studied		
			Proximal	Body	Distal
Douglas	23648	10 Mo	1/4	8/13	4/32
El Gamal	23898	26 Mo	1/2	5/12	2/3
Dorros	3658	16 Mo	8/10	2/7	2/9
Block	23708	3.4 Mo	3/7	7/26	2/7
Marquis	9856	7 Mo	5/8		4/7
Corbelli	2698	8 Mo	10/23	0/7	3/13
Reeder	12859	20 Mo	2/3	3/5	3/8
Cote	23658	8 Mo	3/9	5/21	2/13
Webb	27001	11 Mo	28/47	18/39	22/56
Pinkerton	22798	10 Mo	1/4	3/5	6/16
Total		10 Mo	62/117 53%	51/135 38%	50/164 30%

Dorros and colleagues reviewed PTCA in patients having previous coronary artery bypass surgery. [23388] This study, like most, does not discriminate between PTCA of native artery PTCA and that of bypass graft PTCA for the purpose of long term follow up. Life table analysis of patients with prior CABG followed by successful PTCA revealed an approximate survival rate of 96% at 1 year, 94% at 2 years, 91% at 3 years, 90% at 4 and 5 years, and 87% at 6 years. Event free survival (free from death, myocardial infarction, or coronary artery bypass surgery) was 94%, 90%, 84%, 82%, 78%, and 72% at one to six years, respectively. (Figure 2.7)

Webb and colleagues observed initial success rates were equal in native and graft angioplasties (85% vs 83%) in postbypass patients. [27001] However, long term outcome was better for the native vessel group, who had a lower rate of infarction (4% vs 11%) and need for subsequent reoperation (10% vs 19%). Initial success rates were higher when vein grafts were more recent (<1 year) compared with grafts in place for longer periods. Webb's reported event free survival and overall survival rates were similar to those of Dorros.

Non-surgical patients

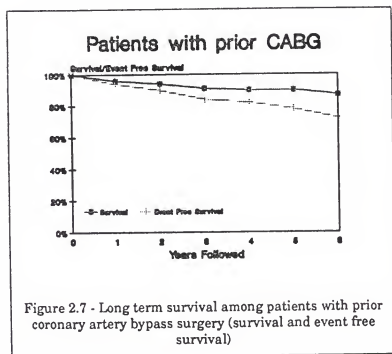
Feldman, *et al*, reported on eight patients thought not to be candidates for either elective or emergency coronary artery bypass surgery. [19191] Primary success resulted in all eight patients. Long term follow up is not meaningful for these patients as the procedure is performed for palliative reasons. Most patients are not considered to have long term life expectancy.

Work Status

A clear measure of procedural efficacy is the extent to which patients are able to return to productive lives. Measurement of work status or return to work may be used as one surrogate for procedural efficacy. The information contained in this section is also relevant to the discussion of costs, as the frequency and expedience with which patients are able to return to work is a measure of indirect procedural costs.

Several studies have explicitly addressed work status. Fitzgerald and colleagues looked at 87 patients employed within six months of the time they underwent angioplasty. At one month following the procedure, 59% had returned to work and 87% had resumed employment at six months. [4483] They observed that those patients with a myocardial infarction, who were less educated, had blue collar jobs, and lacked self confidence were less likely to resume work. Shaw also observed that psychological factors were important in determining six month outcomes. [21921] Holmes and participants in the first NHLBI registry compared successful PTCA patients with those for whom the procedure was unsuccessful, resulting in either bypass surgery or medical management. [22968] Successful PTCA patients returned to work sooner (7 days) compared to those requiring CABG (73 days) and those who received only medical therapy (13 days). At an average follow up of 1.4 years, 85.3% of successful PTCA patients were working, compared to 81.3% and 83.1% of patients surgically or medically managed, respectively.

Ellis compared PTCA with medically treated patients from the Coronary Artery Surgery Study (CASS) (1981-1983). [160] PTCA patients were more likely to continue working at three years



(80.1% vs 62.9%). Other studies have compared PTCA to bypass surgery and have demonstrated that PTCA patients are more likely to return to work than their surgically treated counterparts. [22948, 23398] Only 4.7% of patients in Ellis' study, however, who had retired for medical reasons returned to work following PTCA. [160] Danchin, *et al*, observed that, although procedural success increased, the percent of people returning to work declined over time. This decline was unrelated to severity of illness but was related to patient age. [23838] As older patients are treated with angioplasty, procedural success may be less frequently accompanied by return to work. [23838, 23398]

Chapter 3

COMPLICATIONS

DATA SOURCES

PTCA complication data were drawn from 118 articles. The references include 7 randomized controlled trials, 27 prospective non-randomized trials, 20 prospective non-randomized controlled trials (registries), 13 case-control/adjusted cohort studies, and 51 observational/retrospective investigations.

DEFINITION OF COMPLICATIONS

Complications related to percutaneous transluminal coronary angioplasty are classified into minor complications and major complications. Major complications include myocardial infarction, coronary complications leading to emergency coronary artery bypass surgery, and death. Some investigators include any procedure related myocardial infarction among the major complications [1543, 2659, 3415, 10564, 14362, 14992, 16123, 2116, 22368, 20658, 21474] whereas others include only transmural infarctions within this group [3667, 4396, 12685, 13603, 22005, 20817, 19872]. In the analyses which follow, if the investigator failed to mention "Q-wave" myocardial infarction or "transmural infarction" it was assumed that any myocardial infarction was included among the complications.

The initial National Heart Blood and Lung Institute (NHLBI) registry, which included patients having angioplasty from 1977 to 1981, defined myocardial infarction as at least two of the following: chest pain of long duration; electrocardiographic criteria for myocardial infarction according to the Minnesota code; and an increase in either the creatine kinase level or its coenzyme CK-MB to more than two times the reference interval (i.e., normal range). [18276] In the NHLBI's follow-up registry (1985-1986) a serum creatine kinase value needed to be increased after angioplasty to at least 1.5 times the reference interval with an MB fraction present and new Q-waves present after angioplasty. [19872]

RESULTS

Summary statistics presented are weighted averages of studies which appear not to overlap (i.e., studies not contained within another longer study at the same institution or registry). For complications, data from studies with patients enrolled prior to 1980 were excluded (unless otherwise indicated) from summary statistics because catheter design changed from a nonsteerable form to a steerable one around this time, having an impact on the complication rate.

Major Complications (Overall)

The frequency of complications secondary to PTCA has declined over the last decade. There have been several major changes in equipment design, primarily the introduction of steerable catheters in the early 1980's and the availability of low profile catheters toward the middle of the decade. [18777, 22347] Because of the impact these technical advances have made, reducing the number of procedure related complications, it is dangerous to summarize complications across the decade. Nevertheless, many investigators report series that contain data throughout the 1980s.

TABLE 3.1 - Rates of Any Major Complication (Myocardial Infarction, Coronary Artery Bypass Surgery, Death) in Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates or patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Talley	15430	1981	427	5.2%
Derres	3667	79-86	752	5.2%
Bredlau	1543	80-84	3500	4.1%
Valentine	22368	80-86	500	3.0%
Steffenine	14992	83-85	327	4.9%
Holmes	19872	85-86	1801	7.2%
Finci	4396	83-86	530	10.9% ¹
Kent	22778	77-80	631	18.5% ²
Bredlau	1543	80-84	3500	6.9% ²
Corbelli	23088	80-82	149	22.8% ²

1. Includes fibrillation, death, occlusion
2. Minor complications included

Most series report the rate of myocardial infarction, coronary artery bypass surgery and death separately, making it difficult to identify the frequency with which at least one major complication occurs in any patient. It appears, however, that the occurrence rate of at least one major complication is approximately 3-7%, when myocardial infarction includes subendocardial and transmural events (Table 3.1).

Mortality

PTCA mortality rates have remained low in the 1980s, despite the trend toward selection of more complex, high risk patients. [24048] The mortality rate in large series has consistently remained around 1% (Table 3.2) with an weighted average mortality rate of 0.4%. [1543, 2659, 3415, 3667, 13603, 14362, 22005, 22116, 22368, 21474]

TABLE 3.2 - Mortality Rates in Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates or patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Bredlau	1543	80-84	3500	0.1%
Cook	2659	82-88	258	0.4%
Detre	3415	77-81	1155	1.2%
Detre	3415	85-86	1802	1.0%
Dorros	3667	79-83	204	3.4%
Dorros	3667	83-86	548	0.9%
Finei	4396	83-86	539	0.4%
Meek	10564	77-81	2799	0.7%
Sahni	13603	1985	124	0.8%
Shimizu	14362	81-82	44	0.0%
Steffenino	14993	83-85	327	0.3%
Valentine	16123	80-83	126	0.8%
Simpfendorfer	22005	1981	39	0.0%
Simpfendorfer	22005	1982	100	2.0%
Simpfendorfer	22005	1983	490	0.6%
Simpfendorfer	22005	1984	930	0.6%
Simpfendorfer	22005	1985	1209	0.3%
Simpfendorfer	22005	1986	1205	0.9%
Steffenino	22116	83-86	500	0.2%
Valentine	22368	80-86	500	0.2%
Kent	22778	77-80	631	1.0%
Holmes	19872	85-86	1891	1.0%
Mabin	20658	79-82	244	0.4%
Rapold	21474	80-83	268	0.0%

Coronary Artery Bypass Surgery

Acute occlusion is the event that is responsible in most patients for emergency coronary artery bypass surgery. The early emergency CABG rates were higher than present rates. During the early days of the procedure, emergency CABG was required in approximately 5-8% of patients. With the advent of improved catheter design and trained operators, the rate of emergency CABG has declined in most series to around 2-4% (Table 3.3). The weighted average coronary artery bypass surgery rate is 3.3%. [1543, 2659, 3415, 12685, 13603, 14362, 22005, 22116, 22368, 20817, 21474]

Surgical complications are more frequent among patients who undergo emergency coronary artery bypass surgery following failed angioplasty. [1513, 11830, 4321, 23968, 24028, 15433, 21543, 11011, 21771] Parsonnet observed a 12% surgical mortality rate among patients with failed angioplasty, compared with 1.5% for elective surgery patients. [11830] In the same study, hemorrhage (28% vs 13%), cardiac tamponade (10.5% vs 1.5%), and myocardial infarction (28% vs 9%) were all more frequent among emergency CABG patients following failed angioplasty. In a similar study, Golding observed a 2.5% mortality rate, a 43% myocardial infarction rate, and an 11% hemorrhage rate among 81 emergency CABG patients, all higher than electively operated patients. [23968] Although the complication rates vary among studies, perhaps in part due to the study period and patient selection, all demonstrate significantly increased operative risk among emergently operated

patients when compared to individuals receiving elective CABG either as a primary procedure or following a failed but uncomplicated angioplasty.

TABLE 3.3 - Emergency Coronary Artery Bypass Surgery Rates in PTCA Patients
- Strikethrough type indicates those references not included in weighted averages
(duplicates or patients enrolled before 1980)

	Reference	Years	Number	Percent
Bredlau	1543	80-84	3500	2.7%
Cook	2659	82-88	258	3.1%
Detre	3415	77-81	1155	5.8%
Detre	3415	85-86	1802	3.4%
Dorros	3667	79-86	752	2.5%
Finei	4396	83-86	530	2.3%
Meek	10564	77-81	2700	6.6%
Raizner	12685	80-84	518	4.6%
Sahni	13603	1985	124	5.6%
Shimizu	14362	81-82	44	2.3%
Steffenino	14992	83-85	327	2.8%
Talley	15430	1981	427	5.2%
Valentine	16123	80-83	126	7.1%
Cowley	22828	77-83	3079	6.6%
Simpfendorfer	22005	1981	39	7.7%
Simpfendorfer	22005	1982	100	5.0%
Simpfendorfer	22005	1983	490	5.9%
Simpfendorfer	22005	1984	930	3.1%
Simpfendorfer	22005	1985	1209	1.8%
Simpfendorfer	22005	1986	1205	2.4%
Steffenino	22116	83-86	500	1.6%
Valentine	22368	80-86	500	2.4%
Kent	22778	77-81	631	6.3%
Holmes	20872	85-86	1801	3.5%
Mabin	20658	79-82	244	8.4%
Meier	20817	80-82	608	5.1%
Rapold	21474	80-83	268	13.4%

Myocardial Infarction

PTCA procedural myocardial infarction rates have remained relatively stable at 3-5% (weighted average 3.4%) [1543, 2659, 3415, 14362, 22116, 22368, 20658, 21474], with transmural (Q-wave) infarction rates around 1-2%. (weighted average 1.3%) [12685, 13603, 22005, 20817] (Table 3.4) King and Talley reviewed myocardial infarction rates at Emory University from 1983 to 1987, with similar findings [20286]. Although the myocardial infarction rate has remained fairly constant over time, these figures are somewhat misleading. The PTCA patient profile has changed dramatically since the procedure was first performed in September, 1977. [20283, 24048] PTCA candidates are now older, have more complex disease and are medically less stable than patients who were considered candidates during the early PTCA days.

TABLE 3.4 - Myocardial Infarction Rates in Patients Undergoing PTCA -
Strikethrough type indicates those references not included in weighted averages
(duplicates or patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Bredlau	1543	80-84	3500	2.7%
Cook	2659	82-88	258	7.4%
Detre	3415	77-81	1155	4.9%
Detre	3415	85-86	1802	4.3%
Finei	4396	83-86	530	8.3%
Meek	10564	77-81	2700	4.9%
Shimizu	14362	81-82	44	4.5%
Steffenino	14993	83-85	327	4.3%
Talley	15430	1981	427	5.4%
Valentine	16123	80-83	126	6.2%
Rapold	21474	80-83	268	7.1%
Steffenino	22116	83-86	500	3.0%
Valentine	22368	83-86	500	2.0%
Kent	22778	77-80	631	4.6%
Holmes	19872	85-86	1801	4.3%
Mabin	20658	79-82	244	2.9%
Dorres	3667	79-86	753	2.5%¹
Raizner	12685	80-84	518	2.9% ¹
Sahni	13603	1985	124	1.6% ¹
Simpfendorfer	22005	1981	39	2.6% ¹
Simpfendorfer	22005	1982	100	1.0% ¹
Simpfendorfer	22005	1983	490	2.0% ¹
Simpfendorfer	22005	1984	930	1.6% ¹
Simpfendorfer	22005	1985	1209	0.5% ¹
Simpfendorfer	22005	1986	1205	1.2% ¹
Meier	20817	80-82	608	1.2% ¹

1. Includes transmural MI only

The major complications indicated above are included in most studies which discuss PTCA complications. Other complications, which are either less serious or less frequently reported, appear sporadically in the literature. Acute closure of a manipulated coronary artery is the most common cause of myocardial infarction and the need for emergency coronary artery bypass surgery following PTCA. Acute coronary occlusion itself, resulting from vascular thrombosis or dissection, however, is classified as a "minor" complication because even though in many cases it results in myocardial infarction, bypass surgery, or death, it will be included in these major adverse outcomes when that happens. Some of the more frequently reported "non-major" complications are summarized in table 3.5. Major complications are included in table 3.6.

TABLE 3.5 - Complications of Percutaneous Transluminal Coronary Angioplasty other than Myocardial Infarction, Coronary Artery Bypass Surgery and Death

Author Reference Publ Year	Dorros 19062 1983	Cowley 18804 1984	Bredlau 1543 1985	Holmes 19872 1988	Imburgia 19974 1989	Lewin 9181 1989
N	314	418	3500	1801	43	98
Prolonged Angina	39%	56%	-	5%	-	-
Coronary Occlusion	22%	36%	-	5%	-	-
Coronary Spasm	20%	31%	-	1%	-	1%
Coronary Dissection	14%	32%	-	5%	4%	-
Ventricular Arrhythmias	10%	-	2%	1%	4%	5%
Coronary Embolism	0.6%	1%	0.1%	-	-	3%
Branch Occlusion	1%	-	2%	2%	-	-
Perforation/Tamponade	-	0.6%	-	-	2%	-
Hypotension	10%	-	-	-	4%	5%
Non-Coronary Artery Damage	-	-	1%	-	-	1%
Bleeding ¹	4%	-	0.3%	-	18%	-
CNS Event ²	2%	-	<0.1%	-	2%	-
Pulmonary Edema	0.3%	-	-	-	4%	-

1. Bleeding Requiring transfusion

2. Central Nervous System Event-Cerebral Vascular Accident/Stroke

Chronic Stable Angina

Patients with chronic stable angina are considered to be prime candidates for angioplasty, provided their coronary anatomy is amenable to balloon dilatation. Most general PTCA studies include a large number of patients with chronic stable angina. Some studies have explicitly segregated out chronic stable angina patients and reported findings separately.

The first National Heart, Lung and Blood Institute (NHLBI) registry reported a major complication rate of 9.3% among their 666 patients with chronic stable angina. [18276] The total myocardial infarction rate is approximately 3-5%. (weighted average 4.3%) [7072, 7534, 12037] Simpfordorfer and colleagues reported a 0.8% transmural myocardial infarction rate following angioplasty among 124 patients at least 70 years old with chronic stable angina. (Table 3.7)

TABLE 3.6 SUMMARY TABLE OF COMPLICATIONS ARISING IN PATIENTS UNDERGOING PTCA FOR INDICATIONS SPECIFIED (DETAILS DESCRIBED IN TEXT)

	Any Complication	Transmural Infarction	Non- Transmural Infarction	CABG	Mortality
Large studies		1.3%	3.4%	3.3%	0.4%
unspec indications					
Chronic Stable		0.8%	4.3%	3.9%	0.3%
Angina					
Unstable	8.0%	0.8%	8.0%	3.3%	1.5%
Angina					
Total	1.7%	0.5%		0.9%	0.6%
Occlusions					
Infarction w/o		4.4%		3.6%	5.9%
Thrombolysis					
Infarction					
w/Thrombolysis					
Immediate PTCA	8.5%		3.7%	4.4%	1.5%
Delayed PTCA	4.6%		2.8%	3.6%	0.9%
Cardiogenic					41%
Shock					
Asymptomatic	3.9%	0%	1.0%	4.0%	0%
Patients					
Elderly	4.4%	1.1%	5.6%	2.3%	1.5%
Patients					
Single	5.5%			2.7%	0.3%
Vessel					
Multiple	8.0%	1.8%		2.3%	1.0%
Vessel					
Repeat	2.0%	0.8%		1.5%	0.6%
Angioplasty					
Bypass Graft	5.0%	2.5%		1.5%	2.2%
Angioplasty					

TABLE 3.7 - Myocardial Infarction Rates in Chronic Stable Angina Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (Included only transmural myocardial infarction)

Author	Reference	Years	Number	Percent
Kamp	7534	80-85	334	4.3%
Ischinger	7072	84-86	130	3.1%
Perry	12037	83-87	175	5.1%
Simpfendorfer	23048	81-86	124	0.9% ¹

1. Includes transmural MI only

The rate of coronary artery bypass surgery among chronic stable angina patients is similar to that of the general PTCA population, ranging from 7.1% in the initial NHLBI registry to 2.3-6.1% (weighted average 3.9%) in slightly later studies. (Table 3.8) [7072, 12037, 18276, 23048] Death during hospitalization is an infrequent outcome among patients

with chronic stable angina, occurring in less than 1% of patients (weighted average 0.3%).
(Table 3.9) [12037, 23048]

TABLE 3.8 - Coronary Artery Bypass Surgery Rates in Chronic Stable Angina Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Perry	12037	83-87	175	2.3%
Bentiveglie	18276	77-81	666	7.1%
Ischinger	7072	84-86	115	6.1%
Simpfendorfer	23048	81-86	124	4.0%

TABLE 3.9 - Mortality Rates in Chronic Stable Angina Patients Undergoing PTCA

Author	Reference	Years	Number	Percent
Perry	12037	83-87	175	0.6%
Simpfendorfer	23048	81-86	124	0.0%

Unstable Angina

Patients presenting with unstable angina, defined as ischemic type chest pain at rest lasting at least 15 minutes with or without ST/T wave changes on electrocardiogram but without either new Q waves or elevation of serum myocardial enzymes [7534, 12037, 20631], are at increased risk of premature death and myocardial infarction [23878]. PTCA has evolved as a treatment for many patients with unstable angina. At least one major complication (including transmural and nontransmural myocardial infarction) has been reported in 7.9% (NHLBI, 1977-1981) [18276] to 10.3% [13585] of PTCA patients with unstable angina (weighted average 8.0%). Because of the pathophysiology of the disease, the myocardial infarction rate appears somewhat higher in these patients compared to those with stable angina, ranging from 4.3% to 12% (weighted average 8.0%). [5593, 7534, 12037, 12565, 22122] (Table 3.10) However, the transmural myocardial infarction rate reported by Simpfendorfer in 1988 was approximately 0.8% among 212 patients with unstable angina. [23048] This rate was similar to that reported among patients with chronic stable angina in the same study.

Emergency coronary artery bypass surgery rates are similar in unstable angina patients when compared to those with chronic stable angina. The initial NHLBI registry (1977-1981) reported a CABG rate of 7% among 1273 unstable angina patients. [18276] Subsequent studies have generally reported CABG rates between 2.1% and 3.8% (weighted average 3.3%) (Table 3.11) [5593, 12037, 12565, 23048, 22122] Reported procedural mortality rates range between 1% and 2% (weighted average 1.5%) in most studies of unstable angina PTCA patients. (Table 3.12) [5593, 12037, 12565, 23048]

TABLE 3.10 - Myocardial Infarction Rates in Unstable Angina Patients Undergoing PTCA

Author	Reference	Years	Number	Percent
Gottlieb	5593	Unstated	47	4.3%
Kamp	7534	80-85	334	9.0%
Perry	12037	83-87	105	8.6%
Quigley	12565	82-84	25	12.0%
Steffenino	22122	83-85	89	4.5%
Simpfendorfer	23048	81-86	212	0.9% ¹

1. Includes transmural MI only

TABLE 3.11 - Coronary Artery Bypass Surgery Rates in Unstable Angina Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Gottlieb	5593	Unstated	47	2.1%
Perry	12037	83-87	105	3.8%
Quigley	12565	82-84	25	12.0%
Bentivoglio	18276	77-81	1273	7.0%
Steffenino	22122	83-85	89	2.2%
Simpfendorfer	23048	81-86	212	2.8%

TABLE 3.12 - Mortality Rates in Unstable Angina Patients Undergoing PTCA

Author	Reference	Years	Number	Percent
Gottlieb	5593	Unstated	47	2.1%
Perry	12037	83-87	105	1.9%
Quigley	12565	82-84	25	4.0%
Simpfendorfer	23048	81-86	212	0.9%

Variant Angina

Variant angina, defined as a spontaneous attack of angina with reversible ST segment elevation without an increase in cardiac enzymes, may be present in patients with atherosclerotic disease. Leisch and colleagues observed variant angina in 8% of their 265 PTCA patients. [9034] Complications occurred in 9% (2 of 22) of these patients. Both patients experienced a myocardial infarction; one required emergency coronary artery bypass surgery. The complication rate in patients with variant angina and atherosclerotic disease appears from this small study to approximate that of patients without the condition.

Total Occlusion

Patients with chronic total occlusion of a coronary artery represent a distinct group of PTCA patients. For those patients with viable myocardium distal to an occlusion, revascularization may be indicated for improved cardiac function. Some investigators divide "total occlusion" into complete (100%) occlusion and functional (99%) total occlusion. The latter is defined as faint, late antegrade opacification of the distal vessel segment in the absence of a discernable lumen.

The rate of at least one complication (transmural myocardial infarction, emergency CABG or death) in patients with total occlusion is less than in patients with other types of disease. Rates of 0% (100 patients) [4396] and 1.9% (905 patients) [23408] are reported. The lower complication rates may result from the fact that hearts with already closed vessels may already have sufficient collateral circulation to supply distal myocardium.

Reported transmural myocardial infarction rates in patients with total occlusions range from 0% to 0.6% (weighted average 0.5%). [4396, 23408] Safian, *et al*, had no myocardial infarctions among their 169 patients with total occlusion. [13582] In these same series the emergency coronary artery bypass surgery rate ranged from 0% to 1.8% (weighted average 0.9%) and the mortality rate from 0% to 0.8% (weighted average 0.6%). Safian and colleagues studied patients with functional total occlusion (N=102), total occlusion (N=169) and conventional stenosis (N=711) separately. The myocardial infarction, emergency coronary artery bypass surgery, and mortality rates were 3%, 3%, and 1% in the functional total occlusion group. These results are more similar to those obtained in patients without "total occlusion" than they are to those with total occlusion. [13582]

Acute Myocardial Infarction

PTCA treatment options for patients with acute myocardial infarction include direct angioplasty, without prior thrombolysis, or angioplasty after thrombolysis. When thrombolysis precedes PTCA, patients may be either treated with PTCA immediately or the procedure may be deferred until initial recovery, should this occur.

Without Thrombolysis

The emergency coronary artery bypass surgery rate following PTCA in acute myocardial infarction patients ranges from 2.0% to 11.4% (weighted average 3.6%) (Table 3.13) [2116, 6757, 9805, 11374, 15277]. The 2% CABG rate was reported by O'Keefe and colleagues from the Mid America Heart Institute and included 500 patients. This study included 35 acute myocardial infarction patients with saphenous vein graft occlusions. All surgery occurred in the 465 patients who had native coronary artery occlusions. Mortality rates in these patients are notably higher than in patients without myocardial infarction. Smaller studies report mortality rates between 1.4% and 4.7% [4396, 6757, 9805] with one Eastern European study reporting 5 (12%) deaths in 42 patients [2116]. The Mid America Heart Institute's mortality rate was approximately 8% in 450 patients studied. In these series, the overall weighted mortality average is 5.9%. (Table 3.14) [11374, 22908]

TABLE 3.13 - Coronary Artery Bypass Surgery Rates in Patients Undergoing PTCA for Acute Myocardial Infarction Without Thrombolytic Therapy

Author	Reference	Years	Number	Percent
Caster	2116	Unstated	42	7.1%
Holt	6757	80-85	70	11.4%
Marco	9805	Unstated	43	7.0%
O'Keefe	11374	80-88	500	2.2%
Suryapranata	15277	82-87	114	2.6%

TABLE 3.14 - Mortality Rates in Patients Undergoing PTCA for Acute Myocardial Infarction Without Thrombolytic Therapy - Strikethrough type indicates those references not included in weighted averages

Author	Reference	Years	Number	Percent
Caster	2116	Unstated	42	11.0%
Finci	4396	83-86	50	2.0%
Holt	6757	80-85	70	1.4%
Marco	9805	Unstated	43	4.7%
O'Keefe	11374	80-88	465	7.1%
Hartzler	22908	80-87	446	8.5%

Although all patients in this category have myocardial infarction, Suryapranata and colleagues reported a 4.4% Q-wave myocardial infarction among 114 patients presenting with non-Q-wave infarction. [15277] Significant bleeding is an unlikely complication among acute myocardial infarction patients not treated with thrombolytic therapy. No major bleeding episodes were reported in two studies which explicitly addressed this issue. [2116, 9805]

With Thrombolysis

For patients receiving thrombolytic therapy there are a number of subsequent treatment options available, including angioplasty. Thrombolytic therapy can be administered either by the intracoronary or intravenous route. Studies report results using tissue plasminogen activator and/or streptokinase. Treatment options, discussed in more detail in chapters 5 and 6, include: 1) Immediate PTCA for all patients; 2) Immediate angiography with PTCA only for patients who remain symptomatic following unsuccessful thrombolytic therapy (approximately 25%) and delayed angiography and PTCA if indicated 18-48 hours after TPA for stable patients; or 3) Immediate angiography with PTCA only for patients who remain symptomatic following unsuccessful thrombolytic therapy and delayed angiography and PTCA for those patients with residual clinical or laboratory evidence of myocardial ischemia during their hospitalization.

TABLE 3.15 - Coronary Artery Bypass Surgery Rates in Patients Undergoing PTCA for Acute Myocardial Infarction With Thrombolytic Therapy

Author	Reference	Years	Number	Percent
Stack	14917	84-86	342	4.0% ¹
Rogers	22998	86-88	141	4.3% ¹
Rogers	22998	86-88	108	1.9% ²
Topol	22738	85-86	99	7.1% ¹
Topol	22738	85-86	98	5.9% ²
El Deeb	23448	Unstated	74	2.7% ¹
Guerci	23148	84-87	38	2.4% ²

1. Immediate PTCA 2. Delayed PTCA (See Text)

The Thrombolysis in Myocardial Infarction (TIMI) Phase II-A trial was designed to assess the value and timing of PTCA following thrombolytic therapy for acute myocardial

infarction. [22998] Topol and associates participating in the Thrombolysis and Angioplasty in Myocardial Infarction (TAMI) study group also addressed this issue. [22738]

In the TIMI-IIA trial, the overall 24 hour complication rate among the 141 patients receiving immediate PTCA was 8.5% whereas only 4.6% of 108 patients receiving the delayed invasive strategy experienced such an event. [22998] Although the number of patients in each group was similar at entry, the difference in number of patients receiving PTCA results from events or improvement in the latter group while awaiting delayed intervention. In the TIMI-IIA study, the PTCA associated myocardial infarction rate was 2.8% (4 patients) in the immediate invasive group and 3.7% (4 patients) in the delayed invasive group.

Emergency coronary artery bypass surgery is reported more frequently among immediate PTCA patients than among those in whom surgery is delayed. The TIMI study reported CABG rates of 4.3% and 1.9% in their immediate and delayed surgery groups, respectively. Corresponding rates from the TAMI study were 7.1% and 5.9%. Stack and colleagues at Duke University reported an emergency coronary artery bypass surgery rate of 4% in their immediate surgery patients [14917] and El Deeb, *et al* reported a 2.7% bypass rate among their 74 patients in the Netherlands who received immediate PTCA. [23448] Delayed PTCA was associated with a 2.6% CABG rate in the series reported by Guerci, *et al* at Johns Hopkins University. [23148] The weighted average CABG rate for immediate PTCA following thrombolytic therapy was 4.4% [14917, 22998, 22738, 23448] whereas the delayed PTCA rate was 3.6% (Table 3.15) [22998, 22738, 23148]. Mortality rates among PTCA patients following thrombolytic therapy range from less than 1% to 2% (weighted average 1.4%). [12151, 14917, 22998] The mortality rate reported by Hartzler, *et al* was 7.7% although all six patients who died presented in cardiogenic shock. [19698] (Table 3.16)

TABLE 3.16 - Mortality Rates in Patients Undergoing PTCA for Acute Myocardial Infarction With Thrombolytic Therapy - Strikethrough type indicates those references not included in weighted averages

Author	Reference	Years	Number	Percent
Phillips	12151	79-82	46	0.0%
Stack	14917	84-86	342	1.2% ¹
Rogers	22998	86-88	141	2.1% ¹
Rogers	22998	86-88	108	0.9% ²
Hartzler	19698	Unstated	78	7.7%
El-Deeb	23448	Unstated	74	1.4%

1. Immediate PTCA 2. Delayed PTCA

Thrombolytic therapy is a double edged sword, particularly in patients who are subjected to immediate invasive procedures. In the TIMI-IIA trial, bleeding, sufficient to require transfusion, was observed in 13.8% of immediate PTCA patients yet only 3.1% of delayed PTCA study participants required blood replacement. [22998]

To the extent that PTCA is itself a complication of thrombolytic therapy, 72% of 195 immediate invasive strategy patients ultimately required PTCA whereas 56% of 194 delayed strategy patients ultimately received angioplasty, suggesting that the delayed strategy may obviate the need for some patients to undergo revascularization. [22998]

Cardiogenic Shock

Patients in cardiogenic shock following acute myocardial infarction despite successful revascularization are at increased risk of death compared to patients who are not in shock. The PTCA mortality rate for patients in cardiogenic shock is approximately 41%. [14917, 11374, 9805, 23178] The Mid America Heart Institute observed a mortality multivariate odds ratio of 8.6 relative to patients not in shock at the time of PTCA. Flaker, *et al* observed a 50% mortality rate among 20 acute myocardial infarction patients in cardiogenic shock compared with 4% of 73 who were not in shock during PTCA. [19260]

Asymptomatic Patients

The use of angioplasty in patients with documented coronary artery disease in the absence of anginal symptoms remains controversial. Approximately 70% of ischemic episodes in patients with coronary artery disease are asymptomatic. [25031] Finci and colleagues at the University Hospital in Geneva identified three types of silent ischemia: Type 1 - totally asymptomatic; type 2 - asymptomatic following myocardial infarction; and type 3 - patients with both silent and anginal ischemic episodes. [4399] Five, 27, and 18 patients were studied from these three categories, respectively. Tuzcu, *et al* at the Cleveland Clinic Foundation reported their findings in 34 patients with Type 1 silent ischemia (using Finci's definition). [23478]

Patients with asymptomatic ischemia appear to have a relatively few, although not insignificant, number of complications, compared to patients symptomatic at the time of PTCA. Finci reported a 3.9% major complication rate. The complications occurred in two Type 3 patients who experienced acute coronary dissection, necessitating emergency coronary artery bypass surgery. CABG was required in one patient from the Cleveland Clinical Foundation series. No immediate deaths or myocardial infarctions were reported in the Finci or Tuzcu series. Anderson, *et al*, at Emory University studied 114 patients receiving PTCA for asymptomatic disease, representing 1.7% of their angioplasty patients. [24038] Among these patients, five (4%) required emergency bypass surgery and two (2%) suffered a myocardial infarction. [24038] There were no deaths in this series.

Elderly Patients

Although initial PTCA candidates included only younger individuals, it soon became clear that older patients are reasonable PTCA candidates. Immediate complications range from 3.5% (1983-1986) [8146] to 5.5% (1978-1984) [19068] when only transmural myocardial infarction, bypass surgery and death are included. Among patients older than 60 years in the initial NHLBI (1977-1981) study, the major complication rate was 8.6%, including any myocardial infarction, bypass surgery and death. [18276]

In most studies, the myocardial infarction rate following PTCA for elderly patients is comparable to the general population. The transmural myocardial infarction rate is reported to be between 1% and 3% (weighted average 1.1%). [12685, 16084, 23048, 22908, 19974] The early NHLBI registry [1977-1981] reported a 5.6% overall myocardial infarction rate among elderly patients (N=370). [10564] (Table 3.17)

TABLE 3.17 - Myocardial Infarction Rates in Elderly Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Moek	10664	77-81	370	5.6% ^A
Raizner	12685	80-84	121	2.5% ^{1,A}
Urban	16084	83-86	65	4.6% ^{1,A}
Dorres	19068	78-84	109	2.8% ^{1,B}
Simpfendorfer	23048	81-86	336	0.9% ^{1,B}
Hartzler	22908	80-87	1038	0.8% ^{1,B}
Hartzler	22908	80-87	75	1.2% ^{1,D}
Imburgia	19974	85-87	49	2.0% ^{1,C}
Imburgia	19974	85-87	49	14.3% ^C

1. Includes transmural MI only;
Age: A >65 yrs, B >70 yrs, C >75 Yrs, D >80 yrs

TABLE 3.18 - Coronary Artery Bypass Surgery Rates in Elderly Patients Undergoing PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Moek	10664	77-81	370	6.8% ^B
Raizner	12685	80-84	121	4.1% ^B
Urban	16084	83-86	65	4.6% ^B
Bentivoglio	18276	77-81	395	7.9% ^A
Dorres	19068	78-84	109	0.9% ^C
Simpfendorfer	23048	81-86	336	3.3% ^C
Hartzler	22908	80-87	1038	1.3% ^C
Hartzler	22908	80-87	75	0.0% ^E
Imburgia	19974	85-87	49	8.0% ^D

Age: A >60 yrs, B >65 yrs, C >70 yrs, D >75 Yrs, E >80 yrs

In the initial NHLBI registry, 7.9% of elderly patients undergoing PTCA required CABG. [18276] The weighted average CABG rate in studies after 1980 was 2.3%. (Table 3.18) [12685, 16084, 23048, 22908, 19974] In most studies, procedural mortality rates have remained comparable to the general population with a weighted mortality rate of 1.5%. (Table 3.19) [12685, 16084, 23048, 22908, 19974] Hartzler, *et al* at the Mid America Heart Institute specifically addressed complications in old (>70 years) and very old (>80 years) patients. In their series, the transmural myocardial infarction rates were 0.8% and 1.2%, the CABG rates 1.3% and 0%, and the mortality rates 1.4% and 3.5% for patients older than 70 and older than 80 years, respectively. [22908] These mortality rates compare favorably with those for elective coronary artery bypass surgery among the elderly which are 7.9% and 11% for old and very old (>80 years) patients, respectively.

Younger Patients

Only one series specifically examined PTCA in patients under 36. Among 74 patients, only one (1.4% required emergency coronary artery bypass surgery. [15094] There

were no other procedural complications among the 89 procedures performed in these 74 patients.

TABLE 3.19 - Mortality Rates in Elderly Patients Undergoing PTCA -
Strikethrough type indicates those references not included in weighted averages
(duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Moek	10564	77-81	370	2.2% ^A
Moek	12685	80-84	121	0.8% ^A
Raizner	16084	83-86	65	4.6% ^A
Urban	10068	78-84	100	1.8% ^B
Urban	10068	81-86	336	0.6% ^B
Simpfendorfer	23048	80-87	1038	1.4% ^B
Hartzler	22908	80-87	75	3.5% ^D
Hartzler	22908	80-87	49	6.1% ^C
Imburgia	19974	85-87	49	6.1% ^C

Age: A >65 yrs, B >70 yrs, C >75 Yrs, D >80 yrs

Number of Involved Vessels

Single Vessel

Ideal PTCA patients during the initial PTCA years had discrete, proximal, single vessel disease. The overall complication rate reported for this type of patient in the second NHLBI registry (1985-1986) was 5.5% [19872]. Henderson, *et al*, at Guy's Hospital in London, U.K. reported a higher complication rate (6.8%) although this high rate declined from 8.3% (1981-1984) to 6.0% (1985-1986). [6352]. The major contributor to the high complication rate in this latter study was the high transmural myocardial infarction rate which occurred in 5.9%. In the NHLBI 1985-1986 registry, the transmural myocardial infarction rate for patients with single vessel disease was only 3.5%. Weighted average coronary artery bypass graft and mortality rates are 2.7% and 0.3%, respectively, in these studies combined. [6352, 19872]

Multiple Vessel

The weighted average rate with which at least one complication occurs among patients with multiple vessel disease was 8.0%. [18945, 19227, 19872]. The mortality rate among these patients in five reported series was 1.0%. (Table 3.20) [4396, 18945, 22908, 19872, 23078]. In the same series, transmural myocardial infarction was reported in 1.8%. (Table 3.21). Coronary artery bypass surgery was required in 2.3% of multiple vessel PTCA patients. (Table 3.22) [18945, 19227, 19872, 22908, 20445, 23078]

TABLE 3.20 - Mortality Rates in Patients Undergoing Multiple Vessel PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Dorros	3667	79-86	414	1.4%
Finci	4396	83-86	100	1.0%
Deligonul	18945	83-86	470	2.8%
Dorros	19077	78-83	309	1.0%
Finci	19227	83-86	80	1.3%
Hartzler	22908	80-87	3612	0.8%
Holmes	19872	85-86	926	1.4%
Myler	23078	83-86	494	0.4%

TABLE 3.21 - Myocardial Infarction Rates For Patients Undergoing Multiple Vessel PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Dorros	3667	79-86	414	2.4%
Finci	4396	83-86	100	5.0% ¹
Cowley	18810	79-84	108	4.6% ¹
Deligonul	18945	83-86	470	2.1% ¹
DiSciascio	19041	79-87	54	11.1%
Dorros	19077	78-83	309	4.2%
Finci	19227	83-86	80	5.0%
Hartzler	22908	80-87	3612	0.6% ¹
Holmes	19872	85-86	926	5.2% ¹
Lambert	20445	81-86	274	2.9%
Myler	23078	83-86	494	3.0% ¹
Vlietstra	22434	<1983	100	2.0% ¹

1. Includes transmural MI only

Left Main Disease

One of the most controversial indications for PTCA remains significant disease of the left main coronary artery (or left main equivalent). In the initial Gruentzig study, one of two left main disease patients experienced an early cardiac death. Gruentzig concluded that left main disease was a contraindication to PTCA. This recommendation has persisted. The 1988 American College of Cardiology/ American Heart Association Guidelines on PTCA still list >50% obstruction of the left main coronary artery as an absolute contraindication to PTCA. [19575] It is not surprising that the relative percentage of left main disease among all PTCA patients remains low and has declined from 1.6% in the initial NHLBI registry (1977-1981) to 0.8% in the later registry (1985-1986). [3415]

TABLE 3.22 - Coronary Artery Bypass Surgery Rates in Patients Undergoing Multiple Vessel PTCA - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Derros	3667	79-86	414	3.4%
Cowley	18810	79-84	108	3.7%
Deligonul	18945	83-86	470	6.4%
DiSciascio	19041	79-87	54	1.9%
Derros	19077	78-83	309	3.6%
Finci	19227	83-86	80	3.8%
Wietstra	22434	<1983	100	6.0%
Hartzler	22908	80-87	3612	1.4%
Holmes	19872	85-86	926	4.1%
Lambert	20445	81-86	274	0.4%
Myler	23078	83-86	494	2.8%

The rate of minor complications, dissection, and occlusion among left main coronary artery disease patients is not dissimilar from patients with other coronary obstructions. [19872] The rates of nonfatal myocardial infarction (2.7%) and emergency coronary artery bypass surgery (2.7%) in left main PTCA are also comparable to other patients. The mortality rate, however, is significantly higher among left main disease PTCA patients, reported to be 8.1% compared with 0.2%, 0.9%, and 2.2% for patients with single, double, and triple vessel disease in the 1985-1986 NHLBI registry. [19872] The mortality rate is due to the fact that, although procedural complications do not occur more frequently in patients with left main disease, the results of those which do are catastrophic, given the amount of myocardium supplied by the left main coronary artery.

O'Keefe and colleagues examined three patient subgroups with left main disease: 1) elective "protected" (at least one patent bypass graft to the left coronary circulation); 2) elective "unprotected"; and 3) emergency PTCA in patients with an evolving acute myocardial infarction. [11365] Procedural mortality was 2.4% in the protected group, 9.1% in the elective unprotected group, and 40% in the emergent group. The authors conclude that, although left main coronary artery angioplasty may be reasonable in terms of complication rates, surgical intervention is the treatment of choice for patients with unprotected obstructions.

Vogel, *et al* evaluated elective supported coronary angioplasty, wherein patients are placed on femorofemoral cardiopulmonary bypass support. [23558, 23568] The study included 17 patients with left main stenosis. There were five deaths (29%) among these patients although four patients were also at least 75 years old at the time of supported PTCA. This technique has not gained wide acceptance among those performing PTCA in high risk patients.

Repeat PTCA

Patients require repeat angioplasty for restenosis or disease progression at other anatomic sites. Repeat PTCA complication rates average 2%. [4396, 12571, 20817, 23578] The transmural myocardial infarction rate averages 0.8% (Table 3.23), the coronary artery bypass surgery rate 1.5% (Table 3.24), and the mortality rate 0.6%. (Table 3.25) [4396, 12571, 20817, 23578, 5347] To some extent, repeat PTCA patients have fewer complications because they have already demonstrated anatomy amenable to dilation.

TABLE 3.23 - Myocardial Infarction Rates For Patients Undergoing Repeat PTCA - Strikethrough type indicates those references not included in weighted averages (patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Finci	4396	83-86	70	1.4% ¹
Quigley	12571	85-87	117	0.0% ¹
Williams	17113	77-81	103	2.9%
Meier	20817	80-82	95	0.0% ¹
Alfonso	23578	85-88	74	2.7%

1. Includes transmural MI only

TABLE 3.24 - Coronary Artery Bypass Surgery Rates in Patients Undergoing Repeat PTCA - Strikethrough type indicates those references not included in weighted averages (patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Finci	4396	83-86	70	1.4%
Glazier	5347	80-87	196	3.1%
Quigley	12571	85-87	117	0.0%
Williams	17113	77-81	203	2.0%
Meier	20817	80-82	95	1.1%
Alfonso	23578	85-88	74	0.0%

TABLE 3.25 - Mortality Rates in Patients Undergoing Multiple Vessel PTCA - Strikethrough type indicates those references not included in weighted averages (patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Quigley	12571	85-87	117	0.9%
Williams	17113	77-81	203	0.0%
Alfonso	23578	85-88	74	0.0%

PTCA following CABG

A few studies specifically address complications in patients with stenoses in coronary artery bypass grafts. Many studies group post-CABG patients together whether the angioplasty occurs in a native artery or a bypass graft. For bypass grafts, the overall major complication rate (including transmural myocardial infarctions, emergency bypass surgery or death) was reported to be 5.0% by Dorros, *et al* among their 420 patients. [23388] The average rates for transmural myocardial infarction was 2.5% (Table 3.26), emergency coronary artery bypass surgery 1.5% (Table 3.27), and mortality 2.2% (Table 3.28). [12274, 12859, 23388, 23658] These figures include series that incorporated patients starting in 1979 because studies incorporating only those patients seen after 1980 were few. Killen and colleagues from the Mid America Heart Institute reported an increased operative mortality (17% vs 5.5%) among previous coronary artery bypass surgery patients requiring emergency surgery for failed angioplasty compared with those undergoing emergent coronary artery bypass surgery without previous cardiac surgical treatment. [26001]

TABLE 3.26 - Myocardial Infarction Rates For Patients Undergoing PTCA in Previously Bypassed Vessels - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Dorros	3664	79-86	76	1.3%¹
Reeder	12859	79-84	19	5.3%
Dorros	23388	Unstated	420	2.3% ¹
Cote	23658	81-85	82	3.7% ¹
Marquis	9856	81-83	18	0.0% ¹

1. Includes transmural MI only

TABLE 3.27 - Coronary Artery Bypass Surgery Rates in Patients Undergoing PTCA in Previously Bypassed Vessels - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Dorros	3664	79-86	76	1.3%
Reeder	12859	79-84	19	5.3%
Dorros	23388	Unstated	420	1.4%
Cote	23658	81-85	82	1.2%

TABLE 3.28 - Mortality Rates in Patients Undergoing PTCA in Previously Bypassed Vessels - Strikethrough type indicates those references not included in weighted averages (duplicates and patients enrolled before 1980)

Author	Reference	Years	Number	Percent
Dorros	3664	79-86	76	2.6%
Platko	12274	81-87	98	2.0%
Reeder	12859	79-84	19	5.3%
Dorros	23388	Unstated	420	2.6%
Cote	23658	81-85	82	0.0%

Non-Surgical Patients

Almost all papers which discuss the use of coronary artery angioplasty as a treatment for coronary artery disease point out that surgical backup is mandatory should the patient experience a catastrophic event during the angioplasty procedure. [21636] There are situations, however, where patients with medically intractable ischemic heart disease are not considered surgical candidates. Examples include limited life expectancy (e.g., metastatic neoplasm), extremely poor left ventricular function, and extensive pulmonary disease. In some of these patients, the benefit of palliative revascularization may exceed the procedural risks. Feldman, *et al*, reported on eight patients thought not to be candidates for either elective or emergency coronary artery bypass surgery. [19191]

Gender and PTCA

An initial report from the NHLBI registry suggested that complications were more frequent among female coronary angioplasty patients. [18807] Although in this study the overall frequency of major complications was similar (9.8% vs 9.3%) between men and women, in-hospital mortality rates were higher among women (1.8% vs 0.7%). Including minor complications, women had a much higher total complication rate (27.2% vs 19.4%) compared to men. Nonfatal myocardial infarction and coronary artery bypass surgery rates were similar between men and women in this early report. A later study from the Cleveland Clinic failed to demonstrate any significant difference in the male and female complication rates. [10126]

Chapter 4

UTILIZATION

The first percutaneous transluminal coronary angioplasty was performed on September 16, 1977 by Andreas Gruentzig [20283]. In the ensuing thirteen years, the number of procedures has increased dramatically, in part due to improved technology [22347], greater awareness by the public and the medical community, an increased number of trained invasive cardiologists, and an increase in the number of indications for which angioplasty is considered to be appropriate. [637]. To date, over 1,000,000 procedures have been performed. [25011] Arcidi and colleagues noted that the indications for coronary artery bypass surgery have become more restrictive due to the increased indications and utilization of coronary angioplasty. [442] In this review, by 1986 standards, 56% of 1979 coronary artery bypass surgery patients and 32% of 1984 patients would be angioplasty candidates.

Year	Number of Procedures
1983	32,306
1984	63,315
1985	106,752
1986	159,643
1987	175,680
1988	>200,000
1990	>400,000

The following are the numbers of PTCA procedures performed in the United States between 1983 and 1988 [23038, 20280, 20286].

Figure 4.1 shows the growth in PTCA and coronary bypass procedures over the last decade.

The National Center for Health Statistics National Hospital Discharge Survey for 1987 reported 144,000 single vessel PTCAs without thrombolysis (ICD-9-CM 36.01) and 9,000 single vessel PTCAs with thrombolysis (ICD-9-CM 36.02). Only 3,000 multivessel procedures were recorded in this survey (ICD-9-CM 36.05) [25000].

In 1988 the number of PTCAs performed approximated that of Coronary Artery Bypass Surgery. [23418] Currently, in many parts of the United States, the number of PTCAs now exceeds CABG.

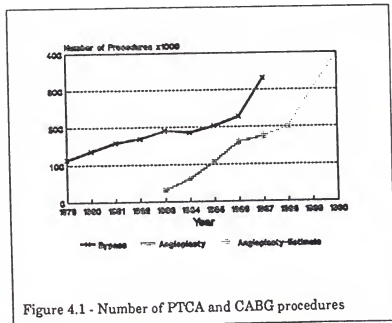


Figure 4.1 - Number of PTCA and CABG procedures

Chapter 5

COSTS

Only a few sources directly address percutaneous transluminal coronary angioplasty costs. Those studies which do generally compare angioplasty costs with those of coronary artery bypass surgery. In 1985 a *Lancet* editorial compared costs for PTCA and bypass surgery. The 1985 editorial commented that, in 1985, the British National Health Service (NHS) cost for coronary artery bypass surgery was £3580. It concluded that, even allowing for restenosis and repeat PTCA, the NHS could save £8 million annually by substituting PTCA for CABG in the 25% of beneficiaries for whom PTCA was a reasonable option in 1985. [19146]

In 1987, Reeder concluded there was insufficient evidence to demonstrate PTCA has reduced expenditures related to myocardial revascularization. [18276] Reeder and colleagues presented data from the Mayo Clinic, based on a 70% success rate and a 33% restenosis rate. The initial cost savings were substantial for PTCA even when surgical standby costs were included (\$5493 vs \$12065), adjusted to 1980 dollars. [22858] Finci suggested a 1:4 initial procedural cost ratio between PTCA and CABG in Switzerland. [19227] Reeder showed that when one year expenditures are taken into consideration, however, the cost differences between PTCA and CABG diminish (\$11,384 vs \$13,387). [22858] Berreklouw and colleagues in the Netherlands compared bilateral internal mammary artery bypass surgery with angioplasty for multivessel disease and suggested that beyond approximately two years the cost benefits from PTCA would be lost, favoring internal mammary artery bypass surgery. [23758]

Most studies that examine long term PTCA costs compare expenses with those of coronary artery bypass surgery, citing modest cost savings. As indications for angioplasty expand, however, patients who would not be considered surgical candidates because of only minimal disease, may be increasingly offered angioplasty as an alternative to medical therapy, increasing the cost for treatment of patients with ischemic heart disease. [18777, 8428, 12856]

Finally, the TIMI II trial demonstrated that immediate PTCA or CABG was not required in all patients successfully treated with thrombolytic therapy for acute myocardial infarction. In the conservative treatment group, only those patients with recurrent ischemia, either spontaneous or induced by exercise testing, were offered angiography and angioplasty. This strategy was not associated with an adverse outcome. Guerci and Ross point out that if this conservative strategy for patients with an acute myocardial infarction was adopted in 1989, approximately \$200 million would be saved annually by eliminating prophylactic angioplasty.

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